A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY AND ACCURACY OF 3D PRINTED MODEL VS 3D RECONSTRUCTED CT SCAN IN PATIENTS WITH FACIAL FRACTURES

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DECLARATION BY THE CANDIDATE

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Dedicated

to

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&

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LIST OF ABBREVIATIONS

2D	2 Dimensional
3D	3 Dimensional
3DP	3 Dimensional printed
ABS	Acrylonitrile butadiene styrene
AP	Antero-posterior
CAD/ CAM	Computer aided design and computer aided manufacturing
CAS	Computer assisted surgery
DICOM	Data imaging and communications in medicine
EOM	Extra ocular movement
FDM	Fused deposition modelling
IOR	Inferior orbital rim
IR	Inferior rectus
ML	Medio-lateral
MMF	Maxillo mandibular fixation
MOW	Medial orbital wall
MPR	Multiplanar reconstruction
MRI	Magnetic resonance imaging

NOE	Naso-orbito ethmoidal
OPD	Out patient department
OR	Operating room
ORIF	Open reduction and internal fixation
PS	Parasymphyseal
PSI	Patient Specific Implants
RE	Reverse engineering
ROM	Restricted ocular motility
RP	Rapid prototyping
RTA	Road traffic accident
SLA	Stereolithography
STL	Standard tessellation language
UV	Ultraviolet
VAS	Visual analogue scale

ABSTRACT

Introduction: Functional and aesthetic outcomes in maxillofacial trauma rely on underlying bony reconstruction. Bending and contouring of fixation plates in facial fractures intraoperatively takes longer operative time, increases soft tissue handling, implant fatigue, worsens tissue edema and may lead to insufficient defect coverage. Therefore, preoperative planning with use of patient specific 3D printed model for facial fractures as a template to prebend plates can aid in better outcomes.

Aim of Study: Our aim is to compare the efficacy and accuracy of 3D printed model vs. 3D reconstructed CT scan in patients with facial fractures in terms of intraoperative ease and accuracy of fixation, intraoperative time, postoperative facial contour symmetry and patient satisfaction.

Materials & Methods: This prospective comparative study involved 40 patients with facial fractures allocated into two groups of 20 patients each. Group A included patients with facial fractures evaluated with CT face followed by 3D reconstruction and immediate surgical repair with conventional plates, bent intraoperatively. Group B included patients unfit for surgical intervention immediately were evaluated with CT face followed by 3D printed model creation for preoperative bending/cutting of plates. Data was collected and compared from preoperative assessment, patient understanding, intraoperative findings, postoperative assessment and patient's level of satisfaction on follow up.

Observations and Result: We found a higher incidence of facial fractures among young population <30 years of age (47.5%) with a male preponderance (92.5%). Road traffic accident was the commonest cause of injury (82.5%). 3D printed model significantly improved the patient's understanding preoperatively when compared to 3D reconstructed CT [9.30±0.92 (Group B) vs. 5.65±1.42(Group A) (p value =0.001)].Patients surgically treated with prebent plates (Group B) when compared to conventional intraoperatively bent plates (Group A) required less intraoperative time (6.30 ± 1.84 min vs. 17.35 ±4.40 min; p value=0.001), less intraoperative manipulations (0.05 ± 0.22 vs 1.55± 0.83) and less additional intraoperative plate trimming (1(5%) vs 5(25%)).Level of satisfaction was significantly higher among patients in Group B (3D printed Model) at one week (p value=0.012) and four weeks (p value=0.001) postoperatively.

Conclusion-This study concludes that preoperative bending of plates for fracture fixation using 3D printed models of injured area as template, when compared to conventional intraoperative bending of plate, has better clinical outcomes, decreases operative time, involves less intraoperative modifications of plate, decreases tissue manipulation and results in better fixation leading to higher level of patient's satisfaction with an additional benefit of improved patient's understanding of their fractures

Keywords: Facial fractures, 3D Reconstructed CT Scan, 3D printed model, Operative time.

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(Dr. Devika Rakesh)

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INTRODUCTION

Patients with complex facial injuries or defects require reconstruction using hardware to restore facial contour and stability. Unstable or comminuted craniofacial fractures need to be reduced and rigidly fixed with titanium plates and screws. Bending and shaping the plates is usually performed by free-hand intraoperatively which may take a lot of operative time. Moreover, bent plates may not snugly fit all the fractures. Therefore, for these cases an appropriate imaging tool used preoperatively or a simulated model prepared preoperatively which can aid in intraoperative fixation of facial fractures is quintessential.

For many years, surgeons relied on two dimensional radiographs of facial skeleton to evaluate facial injuries. Although it is feasible and it's acting as a good initial screening tool but it has its own disadvantages like difficulty in interpretation due to superimposition of bony landmarks and defects, low diagnostic accuracy and limited role in surgical planning.[1] The introduction of 3D Computed tomography visualization, multiplanar reformation and image navigation have helped radiology to be pivotal for many clinical disciplines including management of facial skeleton injuries.[2]

Recent advances in image guided surgeries illustrates how essential radiological evaluation have become as a part of integrated planning along with therapeutic team within different surgical specialties. Three-dimensional imaging created from the original 2D slices has been proved to visualize large comminuted, displaced and complex fractures involving multiple planes, particularly in regard to injuries of midface involving the complex bony structure of orbit.[3] However, despite being highly diagnostic, a better evaluation tool and rapidly interpreted by clinicians than 2D radiographs they still have limited role in small fractures which are limited to one plane. 3D Imaging alone in such cases can give a false negative interpretation.[4,5] Moreso, since these 3D images were created from original 2D slices, artefacts can be produced during reformation

process . Further 3D imaging is limited by visualization of an 3D image on a 2 D flat screen which fails to give a depth perception and accurate involvement of degree of displacement. With this in mind, it is useful to think of 3D imaging as a complementary study that can add important information to multiplanar imaging.

Three-dimensional printing (3DP) also referred to as additive manufacturing or rapid prototyping involves using a complex scientific algorithm and data software which allows to physically create models with high rate of accuracy. [6]

It involves the process of additive manufacturing which requires conversion of computerized tomography or magnetic resonance imaging (MRI) data, which is in data imaging and communications in medicine (DICOM) format into standard tessellation language (STL) format using a proprietary software.[7] Once in a printable format , the file can be imported to the 3D printer for creation of the specific model . The principle of rapid prototyping is to use 3D computer models for the reconstruction of a 3D physical model by the addition of material layers.[8] With additive fabrication, the machine reads data from a CAD drawing and lays down successive layers of liquid, powder, or the sheet material, and in this way builds up the model from a series of cross sections . These layers, which correspond to the virtual cross section from the CAD model joined together, create the final shape. The primary advantage of additive fabrication is its ability to create almost any complex shape or geometric feature.

Its application in medical sciences has become an important advancement and a topic of interest among surgeons due to its advantages in preoperative planning, implant designing, training, and/or education along with better understanding of complex anatomy/morphology or the possibility to create customized implants or surgical guides with reported benefits of increased accuracy of reconstruction, reduced intraoperative time, reduced fatigue of the metal, and ease of use. [9-11]

In field of Plastic Surgery, aesthetic and clinical outcomes of maxillofacial operations majorly rely on underlying bony reconstruction that changes the overlying soft tissues. This makes 3DP an ideal novel technique to be applied for, as current 3DP technology still most commonly uses solid printing material that simulates hard tissues very accurately. Therefore, maxillofacial operations involving bone surgery (plating, recontouring, osteotomies), provide an excellent opportunity to detect and employ emerging 3DP technologies. Another significant benefit is that maxillofacial surgeries require significant symmetry and functionality, both of which can be simulated and virtually modeled with these advancing image processing and computer software.

Facial fractures are a common source of emergency department consultations for the plastic surgeon. Fractures of the middle portion of the facial skeleton are commonly referred to as midface or Le Fort fractures and their treatment remains a challenge for the maxillofacial surgeon. Orbital floor being the least supportive and thinnest structure is most susceptible and commonly involved in mid face trauma. They are often referred to as Orbital 'Blowout' fractures and are the second most common fractures of midface only surpassed by nasal bone fractures. Other associated fractures along with orbital floor are medial or lateral wall fractures, Orbito-zygomatic fractures, Le Fort I, II, and III fractures, Naso-orbital ethmoidal fractures.[12] These complex fractures have a distinct mechanism of injury and most commonly caused by motor vehicle accidents followed by trauma, falls and sports injury. The aim of treatment of these facial fractures is to restore aesthetics and physiological function. While some cases can be managed with conservative care, mostly patients require some type of early or delayed surgical interventions. Among mid face fractures, orbital floor fractures are particularly complex and challenging to manage due to their demanding three-dimensional anatomy, limited intraoperative overview and various complications

associated with these injuries like diplopia, enophthalmos, and ectropion.[12]

Sensitivity and accuracy of detection of these craniofacial fractures and allowing a more detailed analysis. Interpretation of these fractures has become easier with recent advancement and an integrated approach of computed tomography, with post-processing of CT scans to form multiplanar reconstruction (MPR) and 3D reconstruction images. Further Post processing of this digital data acquired by CT scan imaging into 3D volumetric reformatted images or life-sized models using Rapid prototyping/ 3D printing has made quantitative preoperative surgical planning achievable for better outcomes and evaluation of fracture comminution, displaced components and complex fractures involving multiple planes.[13,14]

Patients with midface fractures require reconstruction using implants like titanium plates and screws to restore contour and stability. Bending and shaping these plates is usually performed intraoperatively which are associated with longer intra-operative time, poor navigation of implant, limited stability and higher rate of complications.[15] Therefore, it is imperative to use an appropriate tool preoperatively which can facilitate adequate fixation of orbital floor fractures with minimal tissue handling intraoperatively.

The rationale for this prospective study was to explore the efficacy and accuracy of 3D printed models for patients with facial fractures and compare it with the efficacy of 3D reconstruction scans alone as aids for adequate fracture fixation. We believe that we can achieve improved bony fixation, shorter intra-operative time, superior clinical outcomes without significant increase in overall cost of treatment using 3D printed models.

AIMS AND OBJECTIVES

1. To compare the intraoperative ease of use of fixation device and accuracy of bony fixation in patients with facial fractures undergoing 3D Printed Model vs 3D Reconstructed CT scan preoperatively
2. To compare the intraoperative time (time of insertion of plate) amongst patients with facial fractures undergoing 3D Printed Model vs 3D Reconstructed CT scan preoperatively
3. To compare the post operative outcome clinically in terms of facial contour symmetry and functional stability of facial skeletal framework in the patients with facial fractures.
4. To compare the level of understanding patient had preoperatively about the injuries for which the patient is going to undertake the surgery.

REVIEW OF LITERATURE

Maxillofacial injuries affect a significant proportion of trauma patients. They occur in isolation or in combination with other serious injuries like cranial, spinal, upper and lower body trauma. These injuries have a distinct trauma mechanism and are complex due to its complex anatomy and compact bony and soft tissue structures involved.[16]

Anatomy of facial fractures

Bony injuries of the face are classified by anatomic area involved into upper facial, mid facial and lower facial fractures and are characterized by displacement and comminution. Nearly 75% facial fractures involve mandible, zygoma and nose with nasal fractures being the commonest accounting for 55% of all facial fractures.[17]

Smith H et al.[18] in their study involving 154 patients diagnosed with 443 facial fractures, observed that fractures were frequently present in orbit (32%), malar bone and maxilla (26%), and the nasal bones (19%).

Hwang K et al.[19] in their study involving 2000 patients with facial fractures observed that the most common isolated fracture site was the nasal bone (37.7%), followed by the mandible (30%), orbital bones (7.6%), zygoma (5.7%), maxilla (1.3%) and the frontal bone (0.3%). The largest group with complex fractures included the inferior region of the orbital floor and zygomaticomaxillary complex (14%).

The zygoma is a prominent facial bone and is therefore, prone to injury. Fractures of Zygomaticomaxillary complex are also referred to as tripod or tetrapod fractures depending on the the buttresses involved. [20]. Maxillary fractures have been classified by Le Fort into three patterns :1) Le fort I with a horizontal pattern parallel to the occlusal plane extending from pyriform aperture laterally to the pterygomaxillary junction 2) LeFort II fractures are pyramidal, extending from the pterygomaxillary junction through the zygomaticomaxillary buttress and orbital floor obliquely to the nasofrontal junction 3) Le Fort III fractures are horizontally-oriented

fractures through the upper midface that produce a separation of the cranium from the face, termed craniofacial disjunction. [21] Among midfacial fractures, the frequency of orbital injuries is surpassed only by nasal fractures.[22,23] Fractures involving the orbit are observed frequently in more than 40% of all facial fractures and isolated orbital fractures accounts for 4 % to 16 % of all facial fractures.[24] Orbits are a complex anatomical structural part of face formed by multiple bones, muscles and soft tissues and most importantly surround the organs of vision. The orbital floor is made up primarily of the maxillary bone (orbital process of maxilla), anterolaterally by a portion of the zygomatic bone and posteriorly by a small portion of the palatine bone. The orbital floor and medial wall are most frequently fractured owing to their thinness and lack of support .

Smith H et al.[18] in their study observed that motor vehicle crash was the most common mechanism (47%) for facial fractures .They observedthat the median patient age was 45 years and the median number of fractures was 2. Hwang K et al.[19] observed that the most common age group involved was the third decade of life (29%). Males were more commonly affected than females (3.98:1).

Clinical findings in facial fractures

Koenen L et al.[12] in their study emphasized that history and physical examination play a pivotal role for initial diagnosis and planning further management in any facial trauma patient.

All patients with facial fractures should undergo routine clinical examination for swelling of face, ecchymosis, deformity of face, tenderness, abnormal mobility, step defect at the fracture site, disturbance of occlusion, loss of function, bleeding from mouth, nose or ear and subconjunctival hemorrhage.Typical clinical features of the orbital injuries are periorbital swelling, proptosis in acute stage, enophthalmos (late stage and large fractures), chemosis, ecchymosis, V2 hypoesthesia (area

supplied by maxillary branch division of trigeminal nerve) and subconjunctival hemorrhage.[22] However, some limitations may exist in conducting these tests in patients who present in emergency conditions with extensive soft tissue damage with swelling or are non-responsive and uncooperative due to other concomitant injuries. In these circumstances one has to rely mostly on radiological investigations to decide upon the need for surgical intervention.[25] Smith H et al.[18] reported in their study that a significant proportion of incoming trauma patients may be unable to clearly report their facial injuries due to many factors, including level of consciousness, intoxication, sedation, and respiratory failure . Limitation in using the physical examination to assess facial trauma patients in the immediate post impact time period is that the clinical examination may evolve over time due to changes that occur in the soft tissue. Immediately following trauma, a patient may experience increased swelling of the facial area that has undergone fracture, thereby limiting the examiner's ability to appreciate certain findings. [26]

Role of imaging in management of facial fractures

Absence of adequate pre operative imaging or intraoperative navigation can result in missed complex facial fractures , delayed treatment which in turn increases the need for re-operation , increased hospital stay , increased medical cost ,poor functional and cosmetic outcomes and increased incidence of malunion , non union and aesthetic disfigurement.[27] To avoid these unwanted complications a pre-operative radiological evaluation becomes mandatory.

For decades surgeons relied on two dimensional (2D) radiographs of the facial skeleton to evaluate facial injuries which were relatively difficult to interpret because of the superimposition of bony landmarks and defects.[28] Following advancement in radiology three dimensional images were created from these 2D radiograph slices which assisted in

visualization of large comminuted, displaced and complex fractures involving multiple planes particularly in respect to midfacial injuries.

Computed tomography (CT) is the standard of care for the evaluation of suspected facial fractures because it is readily available, rapidly acquired, and highly accurate in detecting even subtle fractures. Importantly, it is also used to simultaneously evaluate for acute intracranial pathology which may be more urgent. [29]

Shaye DA et al.[30] in their study recommended that imaging should be done in all patients who suffer from facial trauma .CT remains the gold standard choice for detection and defining facial fractures due to its convenience and higher sensitivity (85-99%) [27]and specificity. It allows detection of all facial fractures. Kubal WS et al.[31] recommended coronal and sagittal reconstructions with axial slice thickness of less than 2 mm and 3D reconstruction to optimize maxillofacial assessment.

Role of 3D CT

3D Reconstructed scans help surgeons to better assess the localization of bony fragments and their direction of displacement that are limited to one plane. Further for relatively inexperienced staff the practical interpretation of facial fractures is easier using 3D CT as against conventional radiographs .

Scarfe WC[32] in his study about the imaging in maxillofacial trauma concluded that use of Spiral CT overcomes these limitations which provides rapid acquisition of approximately less than 20 seconds of thin section axial CT data and facilitates multi-planner reformatted (MPR), 2-dimensional (2D) and 3D image reconstruction assisting in diagnosis of fractures better. Due to its accurate representation of orbital anatomy and its spatial relationships, it also helps in surgical exploration, fracture reduction and selection and contouring of rigid reconstruction plates. Therefore, proven to have decreased complications resulting from delays in diagnosis and treatment.

Kaur J et al.[33] in their study included 100 patients of mid face fractures. After clinical examination, patients were subjected to conventional radiographs. To arrive at correct diagnosis and treatment plan, each patient was subjected to 3D reconstruction. Out of hundred patients of maxillofacial trauma 80% were males and 20% were females. Based on the etiology, road traffic accidents (75%) were the most common, followed by assault (16%), fall (7%) and sports related accidents (2%). In 28 cases (28%) 3D CT had significant bearing in final diagnosis and treatment planning of mid face fractures. They concluded that 3D CT is valuable in case of severe facial injury, enabling a clear perception of extent of major fracture line and resulting displacement of fragments. So, this new modality permits preoperative analysis and surgical planning as compared to conventional radiography in case of mid face fractures.

Frame JW et al.[34] in their study observed that the facial injuries often produce gross edema which complicate clinical examination and obscure the underlying bony injuries by producing haziness in conventional radiographs. Whereas with 3D CT imaging, there is no need to wait for facial edema to subside as it displays bony as well as soft tissue injuries even in the presence of edema. Fractures of the mid facial region are often difficult to diagnose on the conventional radiography because of complex anatomy of face and superimposition of thin bones of face which produce ghost artifacts leading to misinterpretation of fractures. Thus, they concluded that Three dimensional CT imaging technology has a dramatic impact on facial injury management.

3D CT despite being highly diagnostic, a better evaluation tool and rapidly interpreted by clinicians than 2D radiographs, it still has limited role in small fractures which are limited to one plane. 3D Imaging alone in such cases can give a false negative interpretation.[4,5] Minor undisplaced fractures are not well shown on 3D because of computerised reconstruction error.[27] Moreso since these 3D images were created from original 2D slices, artefacts can be produced during reformation process.

Further 3D imaging is limited by visualization of an 3D image on a 2 D flat screen which fails to give a depth perception and accurate involvement of degree of displacement. With this in mind, it is useful to think of 3D imaging as a complementary study that can add important information to multiplanar imaging. [4,5]

Role of 3D printed model

The earliest record of 3D printing through the additive process was the Japanese inventor Hideo Kodama in 1981.[35] He developed a rapid prototyping system with a layer-by-layer approach for manufacturing, using a photosensitive resin that was polymerized by UV light. SLA (Stereolithography) was the first 3D printing technique available and the first used in the biomedical field, in 1994. Orthopedic surgery and Oral and Maxillofacial surgery were among the first specialties to adopt this technology.[36]

3D printing also known as Additive manufacturing or rapid prototyping is an emerging technique with a methodology of using three-dimensional CAD data sets for producing live 3D haptic physical model. The basic principle of rapid prototyping (RP) is to use a 3D computer model for reconstruction of a 3D physical model by the addition of material layers [37]

3D printing and computer software planning are gaining extended applications in facial plastic and reconstructive surgery including craniofacial injuries. The combination of computer-aided design and manufacturing (CAD- CAM) has provided surgical models for pre surgical planning, plate contouring, and customized patient-specific implants (PSIs). Reported benefits have included increased accuracy of reconstruction, decreased intraoperative time, decreased fatigue of the metal, and ease of use [9– 11].

Hsieh TY et al.[38] reviewed studies on role of 3D printing and demonstrated 3D printing applications in surgical planning including accurate anatomic biomodels, surgical cutting guides in reconstruction,

and patient-specific implants fabrication. Emerging research in 3D biomaterial printing have led to the development of biocompatible scaffolds with potential for tissue regeneration in reconstruction cases involving significant tissue absence or loss.

Compared to the technology in the 1980s when 3DP was first developed, nowadays it is considerably cheaper, easily accessible and less time-consuming. A great variety of printing material allows for mechanical properties and appearance accustomed to specific applications. More importantly, accessibility of robust 3D modelling software and powerful computer processors enables 3D models to be created at ease with typical desktop workstations.[39]

Management of facial fractures has evolved greatly from use of arch bars for fixation to a rigid and stable fixation using plating system.[40] The material of choice for facial fracture reconstruction plates is titanium due to its advantages including availability, biocompatibility, rigid fixation, and low susceptibility to infections.[41] Its disadvantages are that it can be difficult to bend, to insert, and to contour. [42]

The anatomical areas of the face which are difficult to access and have surface irregularities making moulding of implants difficult are ideal zones where prebent plates can be used using 3D printed models and orbit is one such area. The surface of the floor of the bony orbit has unique undulations and it would be very difficult to accurately shape an implant manually without the use of 3D printed moulds. Since visualization of the implant is limited when placed in the orbit, confirmation of fit is difficult as well.

Use of CAD and 3D printing for skills training was described by creating patient specific models including pediatric costal cartilage model for microtia have been described in various studies in the literature.[43] Besides better understanding for surgical training 3D models have been also associated with intraoperative ease and reduced operative time. King et al. [44] compared the intraoperative time and operating room costs

between patients with mandibular fractures treated with traditional adaptation and fixation and patients treated with preadapted plates created with on-site 3-dimensionally printed models. The 38 patients included in the study had a mean age of 39.6 years, and male patients comprised 81.6%. The mean time for intraoperative plate adaptation was 22.8 ±2.1 minutes in the control group and 6.9 ± 0.3 minutes in the experimental, 3D printed group ($P < .0001$). In the experimental group, 4 patients (21%) required a single intraoperative corrective bend. The calculated average cost per patient based on the average operating costs was $2,306.45 in the control group and $698.00 in the experimental group. The calculated average cost per patient based on the average operating costs was also significantly higher in the control group thus concluding that use of 3D printers for fabrication of models to prebend maxillofacial reconstruction plates is associated with decreased operating room time and costs.

Singare S et al.[45] reported the benefit of Computer Tomography (CT), reverse engineering (RE) and rapid prototyping (RP) in individual implant production for maxillofacial surgery. They studied some clinical cases where virtual models had been used for surgical preparations and 3D printing models for manufacturing of implants. All their cases were treated with reconstruction implant prefabricated using 3D printing. There were no complications observed in any of the patients who underwent reconstruction using 3D Printing implants in 10 year of follow up, all of these patients regained full oral function .They concluded, that use of 3D printing technique has facilitated the mandible reconstruction surgery and offers a better life to the patients.

Xeu R et al.[46]conducted a study involving 8 patients with orbital-maxillary-zygomatic reconstruction after trauma or resection of space-occupying lesions. All the patients admitted for orbital-maxillary-zygomatic reconstruction underwent preoperative 3D dual-source 64-slice spiral computed tomography. The CT scan was evaluated and images were

processed into data files in DICOM format. Simpleware 6.0 software (Simpleware Ltd, Exeter, UK) was used to generate 3D images and transfer DICOM data to structure triangulation language file in workstation for digital manipulation and generate a life-size 3D skull model. Three-dimensional bone disease models of the patients were assessed to show the real bone fractures or localize the space-occupying lesions. Manual surgeries were rehearsed on the models and the fractured bones or bone resection lines were labeled; therefore, surgeons appropriately visualized the orbital-maxillary-zygomatic areas and were familiar with the surgical plans. Titanium or absorbable mesh and plates were anatomically premoulded using the mirror imaged 3D models. Patients with trauma achieved anatomical reduction at fractured sites and got precise reconstruction of the bone defect. Precise resection and reconstruction was performed on patients diagnosed with space-occupying lesions. The procedures of surgeries were fluent and smooth according to the preoperative planning. The procedure time was greatly reduced due to surgeons having a better understanding of anatomical position in the operating area prior to the surgery. All patients received improved cosmetic shape of the face and orbit. There were no postoperative complications such as diplopia, infection, foreign body reaction, exophthalmos, enophthalmos, disordered occlusal relationship, and hematoma. Patients were satisfied with the functional and esthetic outcome during the follow-up.

Sinha P et al. [47] conducted a study to explore the potential application of 3D printed short segment mandibular template in management of complex mandibular fractures which included 3 patients .They observed the median (range) preoperative time for plate contouring was 8 (3-29), 5 (2-18), and 10 (2-19) minutes for the angle, body, and symphyseal/ parasymphyseal segments while the intraoperative times were 7 (1-14), 5 (1-30), and 7 (2-15) minutes, respectively. They observed shortened overall operating times, even in the hands of residents with minimal experience in open

reduction and internal fixation of facial fractures . They thus, concluded that use of 3D printed models results in considerably reduced operative room cost and time.

Metzger et al.[48] were the first to conduct a cadaveric study to evaluate the use of prebent 3dimensional titanium mesh implants for orbital floor and medial wall reconstruction in 8 human cadaveric heads (n=16 orbits). Result of this pilot study showed prebent 3dimensional titanium mesh implants provide accurate reconstruction of orbital floor and medial orbital wall fractures with mean implant error was <1 mm for all orbits studied (Mean values- 0.68+/-0.63 mm for the unfractured side and 0.93+/-0.82 mm for the fractured side). No significant differences were found between orbits when evaluated for side of injury, gender, or size of defect.

Scolozzi P et al.[49] evaluated the accuracy and predictability of new three-dimensionally preformed titanium mesh plates for posttraumatic orbital wall reconstruction in 10 patients with isolated blow-out orbital fractures. A three-dimensional preformed titanium mesh plate (0.4 mm in thickness) was selected according to the size of the defect previously measured on the preoperative computed tomographic (CT) scan examination and fixed at the inferior orbital rim with 1 or 2 screws. The accuracy of plate positioning of the reconstructed orbit was assessed on the postoperative CT scan which revealed a high rate of success (90%) with an acceptable rate of major clinical complications (10%) and an anatomic restoration of the bony orbital contour and volume that closely approximates that of the contralateral uninjured orbit with an accuracy to within 2.19 cm^3 (2.19 to 2.5 cm^3).

Lee KM et al.[50] conducted a study in an East Asian Population to show Three Dimensional Prebent Titanium Implant for Concomitant Orbital Floor and Medial Wall Fractures which concluded Three Dimensional Prebent Titanium Implant were safe and effective in near-normal restoration of the orbital floor and wall contour in South Korean population with satisfactory functional and aesthetic outcomes with mean enophthalmos showing

significant improvement from preoperative to postoperative evaluation (1.167 ± 0.4596 mm vs. 0.4545 ± 0.1575 mm; P = 0.0456) and no postoperative complications, such as a foreign body reaction, diplopia, EOM limitation, or visual acuity decrease post-operatively and during follow-up period.

Zhang X et al.[51] were able to demonstrate application of Three-Dimensional Printing technology in the orbital blowout fracture reconstruction in 12 patients with orbital floor and/or medial wall fractures. Preoperative CT data were processed to generate a 3D reconstruction of both affected and unaffected orbit, using the non affected orbit as a template. Position, size as well as scope of the defect was measured and accordingly the shape and bending of titanium mesh was done. The need for manual adjustment was avoided by meticulous preoperative titanium mesh planning. All patients underwent reconstruction of the medial wall fractures alone or together with floor fractures, via individual titanium mesh using a 3D printer, using a lower eyelid incision without difficulty and obviating the need for manual adjustment with preoperative orbital volume (2.57±0.43 ml) and protrusion (2.21±0.90 mm) significantly higher than the preoperative value (0.09 ± 0.60 ml) (P< 0.001) and (0.12± 0.50 mm) (P< 0.001) respectively.

Park EK et al.[52] showed how 3D printing was used successfully in the treatment of blowout and other fractures around the orbit, with the use of moulding of various titanium implants to retain structural and cosmetic appearance. Their techniques allowed them to show no significant difference in the volume of the non injured and reconstructed orbits.

Weadock WJ et al.[53] used 3D printed models to create moulds for shaping implants for surgical repair of orbital fractures among 3 patients in which thin section of computed tomography (CT) images were first taken into a clinical 3D visualization software, and 3-Dimensional printed models were created. The three patients treated using 3D printed moulds had excellent outcomes, with decreased postoperative edema and rapid

resolution of ocular misalignment/strabismus. Surgical times were decreased from an average of 93.3 minutes using standard implants to 48.3 minutes following adoption of 3D printed moulds with an improving fit, reducing tissue handling and postoperative edema, and reducing surgical times.

Pang SSY et al.[39] reported two cases with orbital floor fractures complicated by diplopia in which open reduction and orbital floor reconstruction with Medpor implant was performed with the guidance of a 3D printed customized model of the orbital floor defect. The operative duration was 1 h 7 min in first case and 1 h 10 min in second case which on comparison with previous 15 consecutive orbital floor re-constructions with implants was reduced by nearly 30 min with aid of the 3D printed bone model. Both patients had satisfactory results over follow-up for over a period of 2 months with normal extraocular eye moments and resolution of diplopia.

Kozakiewicz M et al.[54] included six patients with facial trauma in their study. First, 3D virtual models and then physical models were created. These were used as templates to shape the titanium mesh and then intraoperatively as guides to aid correct implant placement in the orbit. They observed a significant improvement in preoperative symptoms in 3 cases and total recovery in three cases after treatment. They concluded that use of 3D bent titanium implants resulted in greater accuracy, shortened operation time and better understanding of orbital disruption.

Zhong N et al.[55] in their study highlighted the potential disadvantages of 3D printing included the additional cost, need for 3D software engineering, and a lengthy turnaround time making them impossible to receive the models in time for acute surgery . The lengthy turnaround time includes the time required to capture anatomical scans, create a virtual 3D prototype, 3D print of the material layer by layer and finally modify the final structure. This can also vary between 1 hour and 24 hours, depending on the size of the object and the resolution of the printing.

Technically, the 3D software engineer needs to be proficient in thresholding and segmentation. This involves selecting, defining (or merging) the relevant fracture fragments and smoothening out pixel edges before printing. Problems encountered with software bugs and printing failures also amount to a major limitation as far as use of 3 D printed models is concerned. Resterilization of the prebent plate may add to the cost of surgery and is therefore another time and resource consuming process leading to further delay in surgery.[56]

Additionally a range of unwanted artefacts that create distortions on medical models have been identified in a study by Winder J et al.[57]. These include data import, computed tomography gantry distortion, metal, motion, surface roughness due to support structure removal or surface modelling, and image data thresholding. The source of the artefact has been related to the patient, imaging modality performance, or the modelling technology. They thus recommended that models of human anatomy generated by medical rapid prototyping should be subject to rigorous quality assurance at all stages of the manufacturing process.

Despite the potential cost limitation, the price of 3D technology is continuing to be driven down in terms of the price of devices, materials and software.[58] The major limitations including time and cost, may be offset by decreased operating times and collaboration between departments to diffuse in-house printing costs.

Over the years the goal of maxillofacial surgeons worldwide has been to achieve near perfect reduction of comminuted facial fractures to achieve best possible aesthetic outcome. To attain this goal there have been advances in the imaging techniques and management protocol of facial fractures ranging from plain CT to 3D reconstructions , further expanding to the the use of 3D printed models preoperatively.[30] Further advancements include use of PSI (patient specific implants) [59]and real time surgical navigation systems.[60]

The use of computer-designed PSI enables a more accurate reconstruction of maxillofacial defects, eliminating the usual complications seen in preformed non custom made implants and resulting in higher patient satisfaction with high cost as its main drawback.[61] Computer-designed PSI offers higher accuracy and defect adaption, enhanced stability, more predictable outcomes, and better facial contour refinement.[62,63]

Computer-assisted surgery (CAS) or Real-time surgical navigation systems is a new technology introduced in facial skeleton reconstruction based on the patient's preoperative imaging. Surgical image guidance systems allow surgeons to see instrument position in real-time, in relation to anatomic landmarks identified on imaging.[60] In addition, intraoperative navigation helps reduce unnecessary surgical manipulation and eliminate dangerous dissection close to the optic canal.[64,65]

Kim JH et al.[66] in their study compared the efficacy of the conventional manual-bending implant and the 3D-printed standardized implant in order to verify the clinical utility of the fabricated 3D printed orbital implant. The authors evaluated medical records and 3D-CT scans of patients with inferomedial orbital fracture retrospectively. Selected patients were divided into two groups. Group A underwent surgery with the 3D-printed standardized implant, while group B was treated using a manual technique to mould and trim the implant. A total of 32 patients was included in this study, 16 in each group. The volume of the preoperative lesion side was significantly different from that of the normal side or postoperative lesion side within each group. The volume of the postoperative lesion side was not statistically different from that of the normal side in Group A, but this volume was significantly different from that of the normal side in Group B. They concluded that 3D-printed standardized implant provides surgical efficacy to restore inferomedial orbital fracture and has superior surgical outcomes to the manual-bending implant.

Intraoperatively bent plates vs 3D printed model assisted prebent plates

Kim YC et al. [67] evaluated the accuracy of blowout fracture reduction using 3D printed rapid prototyping (RP) skull modeling. This comparative study was performed for 82 patients (46 medial and and 36 inferior orbital wall fractures) who underwent post-traumatic orbital wall fracture reduction between 2012 and 2014. Patients were divided into two groups according to the use of 3D-printed RP skull model reproduced by mirroring technique, onto which a titanium mesh was anatomically moulded. Using computed tomographic scans, the areas of pre- and postoperative orbital wall defect, the layout angles of the titanium mesh, and the gap lengths between the implant and fracture margin were compared between the two groups.. Bone defect area of the RP group was significantly reduced in comparison with that of the conventional group (8.03±3.5% versus 18.7±15.41% for medial wall fractures, (7.14±5.74% versus 12.8±4.92%for inferior wall fractures, respectively, $p< 0.01$). In the RP group 95.5% of patients had no enophthalmos and 4.5% had mild enophthalmos and diplopia, compared to 86.8% with no enophthalmos and 7.9% with mild enophthalmos and 13.2% with diplopia in the control group. They concluded that more accurate restoration of traumatic orbital wall fractures can be achieved using patient-specific 3D printed RP skull models.

Raisian et al.[68] conducted a randomized clinical trial among 10 patients to compare customized titanium prebent mesh based on the 3D printed model vs. manual intraoperative bending of titanium mesh for reconstructing of orbital bone fractures. CT scans were used for 3D reconstruction of both affected and unaffected orbits using which a 3D printed template of mirrored un-affected orbit was produced to mould the titanium mesh in the intervention group (n=5) and compared with conventional group in which titanium mesh was bended only manually and intra-operatively by surgeon and positioned over the bony defect. The study showed a significant difference in mean enophthalmos after surgery

and concluded that placement of patient-specific titanium implant for reconstructing of orbital bone fracture leads to better outcomes when compared to manual bending in terms of enophthalmos and other complications.

Azuma M et al.[69] compared aesthetic outcomes of prebent mandibular reconstruction plates using 3D printed models versus intraoperative plate bending in 28 patients. In their study, 12 patients were reconstructed with 3D printed model based prebent plates and 16 patients were treated with intra-operative plate bending. The resected site was then compared to the unaffected side using panoramic tomography postoperatively to determine symmetry. They observed that the group treated with 3D printed prebent plates demonstrated significantly better postoperative facial contour symmetry ($P<0.05$) than the group treated with intraoperative bent plates.

MATERIALS AND METHODS

This prospective study included 40 patients with facial fractures who attended the Emergency or OPD at Dayanand Medical College and Hospital, Ludhiana and were willing to be a part of the study after satisfying the inclusion criteria

Inclusion criteria:

(1) Patients with facial fractures

(2) Patients with comminuted displaced fractures

(3) Patients who were not fit to be taken up for immediate surgical intervention (Group B)

Exclusion criteria:

(1) Patients not fit for General Anaesthesia

(2) Situations where delay of surgery was going to be detrimental for patient's health

(3) Patients with coagulation disorders

(4) Isolated non comminuted fracture of any facial bone

(5) Patient with isolated nasal bone fracture

The patients in the study were divided into two groups of 20 patients each:

Group A –Patients with facial fractures who could be immediately taken up for open reduction and fixation of facial fractures.

Group B- Patients with facial fractures who could not be immediately taken up for any surgery.

Group A patients had CT face with 3 D reconstruction done.

Group B patients had CT face done in our institution and the CT data which was in DICOM (data imaging and communications in medicine) format was converted into STL (standard tessellation language) format using a proprietary software which in our case was Mimics17.0 which was imported to the 3D printer for creation of the specific 3D printed model by laying down layers of Acrylonitrile butadiene styrene (ABS) using FDM (Fused Deposition Modelling) technique. These 3 D printed models were

procured from PEC (Punjab engineering college) Chandigarh. It took 24-48 hours for planning and printing of the 3D models

Preoperatively the patients were examined for any obvious signs of muscle entrapment or globe displacement (in patients with orbital floor fractures) clinically and the findings were correlated on the CT and 3D reconstructed scan in group A patients and with the findings of 3D printed models in group B patients .

Patients in both the groups were taken up for open reduction and internal fixation of facial fractures.

In Group A patients, the fracture reduction and fixation was done in the standard fashion i.e. using fixation plates that were bent/ cut by free hand intraoperatively

While in Group B patients, the printed models made were used as templates for bending and shaping the plates preoperatively .

A fixation plate was selected and adapted to the printed model preoperatively. The plate was then processed and sterilized to allow for human implantation. Once in the OR, the fracture sites were accessed in the standard fashion, subciliary incision was used for exposure of orbital floor fractures and standard gingival incision for accessing other fractures and the plate adaptation evaluated. After complete exposure of the fracture site the fractures were reduced to their anatomical position, the herniated orbital contents (in case of orbital floor fractures) were reduced and repositioned. The fracture fixation was then done with plates which were previously contoured in all Group B patients. Any additional modification (cut/ bend) made to the plate intraoperatively was noted. In Group A patients the contouring of the plates was done intraoperatively. The fixation of the plates was done using 6 mm locking titanium screws, following which hemostasis was ensured and then layered closure of the incision was done.

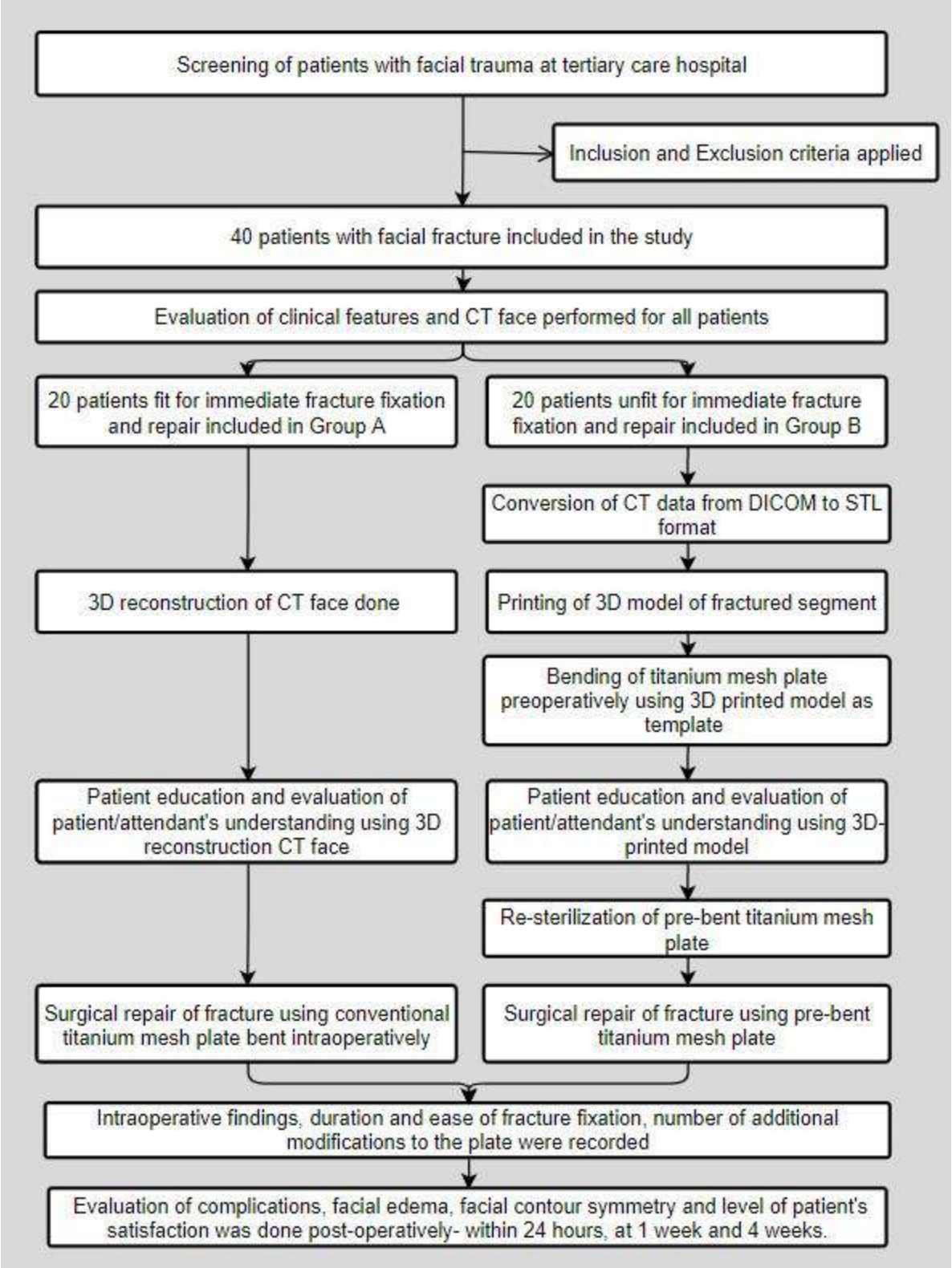
Outcome: Preoperative understanding of the patients/attendants in both the groups about the injuries for which they are going to undertake the

surgery was assessed using a score of 0 to 10 , with a score between 0-3 interpreted as poor, 4-7 as fair and 8-10 as good understanding and was compared among both the groups.

Various intra-operative parameters like time needed for fracture fixation starting when the fracture was completely reduced and ending when the last screw was placed, number of adjustments required for plate adaptation, additional bending and cutting of plate to fit fracture site, accuracy of fixation of fractures, and ease of use of fixation plates were compared among the patients of the two groups

Post-operatively the patients in both the groups were assessed for any persistence of preoperative symptoms, appearance of new symptoms and operation related complications. Facial contour symmetry was assessed clinically and patient satisfaction, subjectively in both the groups using Visual analog scale (VAS) numbered from 0 to 10, with not satisfied being 0-3, satisfied being 4-7 and highly satisfied being 8-10 and compared among patients of the two groups on follow up visits (week1, week4).

STATISTICAL ANALYSIS: Data was described in terms of range; mean±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups was done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test was performed and exact test used when the expected frequency was less than 5. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.


Screening of patients with facial trauma at tertiary care hospital
Inclusion and Exclusion criteria applied
40 patients with facial fracture included in the study
Evaluation of clinical features and CT face performed for all patients
20 patients fit for immediate fracture fixation and repair included in Group A
20 patients unfit for immediate fracture fixation and repair included in Group B
Conversion of CT data from DICOM to STL format
3D reconstruction of CT face done
Printing of 3D model of fractured segment
Bending of titanium mesh plate preoperatively using 3D printed model as template
Patient education and evaluation of patient/attendant's understanding using 3D reconstruction CT face
Patient education and evaluation of patient/attendant's understanding using 3D-printed model
Re-sterilization of pre-bent titanium mesh plate
Surgical repair of fracture using conventional titanium mesh plate bent intraoperatively
Surgical repair of fracture using pre-bent titanium mesh plate
Intraoperative findings, duration and ease of fracture fixation, number of additional modifications to the plate were recorded
Evaluation of complications, facial edema, facial contour symmetry and level of patient's satisfaction was done post-operatively- within 24 hours, at 1 week and 4 weeks.

Picture 1: Visualization of the study design

OBSERVATION AND RESULTS

This prospective study was conducted at Dayanand Medical College Ludhiana, involving a total of 40 patients meeting inclusion criteria. The patients were divided into two groups of 20 each: Group A included patients with facial fractures who underwent CT face followed by 3D reconstruction and were taken up for fracture fixation immediately using plates in the standard fashion. Group B included patients who were unfit to be taken up for surgical intervention immediately and underwent CT face followed by 3D printed model creation which was used for preoperative bending/cutting of plates before the patient was taken up for the surgery . Patients in both the groups were followed up immediately within 24 hours, at 1 week and 4 weeks post-operatively and intraoperative and postoperative variables were compared in both the groups.

1. Age

Over all mean age of patients in our study was 31.07 ±12.16 years. The mean age of patients in Group A was 33.60±9.57 years and in Group B was 28.55±14.10 years. Majority of the patients in Group A were in the age group of 31-50 (65%; 13) whereas majority of patient in Group B were <30 years of age (65%; 13) as depicted in Table 1.

Age distribution		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Age (in years)	< 30	6	30%	13	65%	19	6.468	0.039
	31-50	13	65%	5	25%	18		
	> 50	1	5%	2	10%	3		
Total		20	100%	20	100%	40		

Table 1 Shows distribution of patients according to age in Group A and Group B

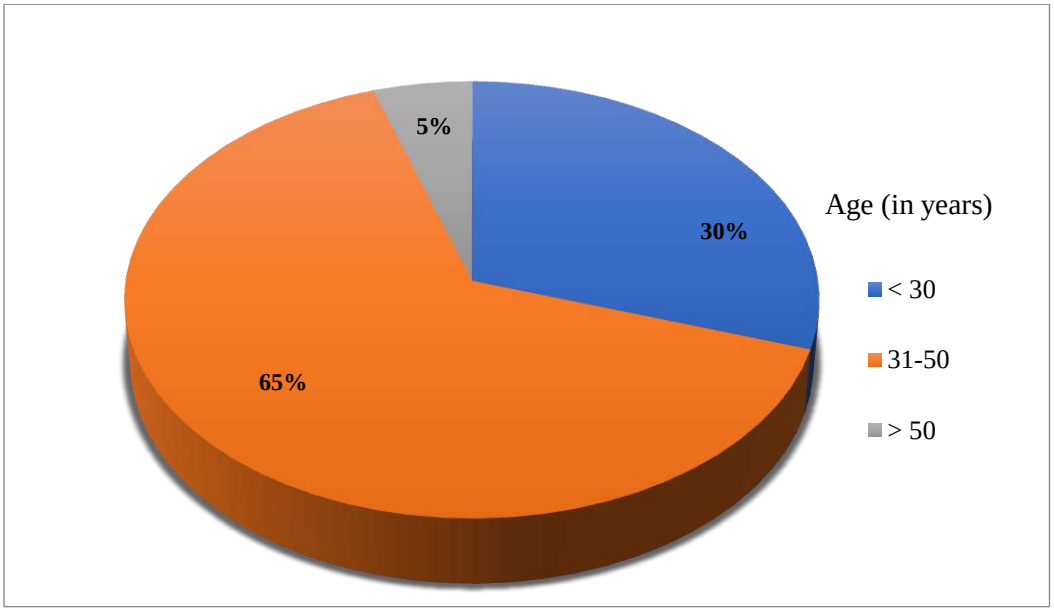


Figure 1 Shows distribution of patients according to age in Group A

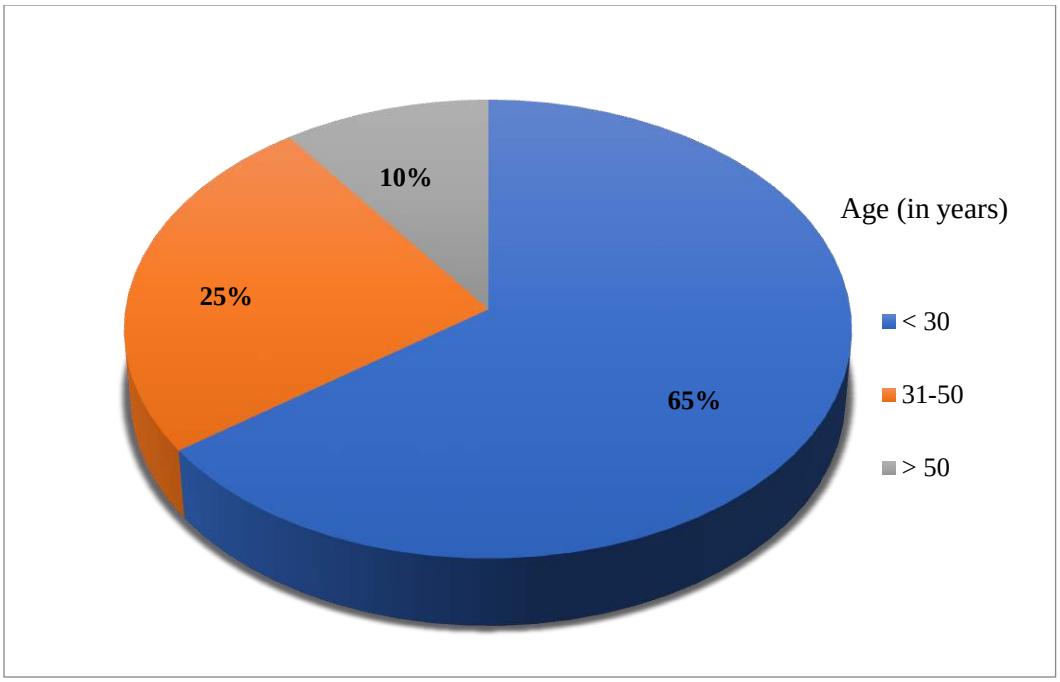


Figure 2 Shows distribution of patients according to age in Group B

2. Gender

Our study showed a male predominance in both the groups with 18 (90%) male patients in Group A and 19 (95%) male patients in Group B as depicted in Table 2.

Gender distribution		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Gender	Female	2	10%	1	5%	3	0.360	0.548
	Male	18	90%	19	95%	37		
Total		20	100%	20	100%	40		

Table 2 Shows distribution of patients in Group A and Group B according to Gender

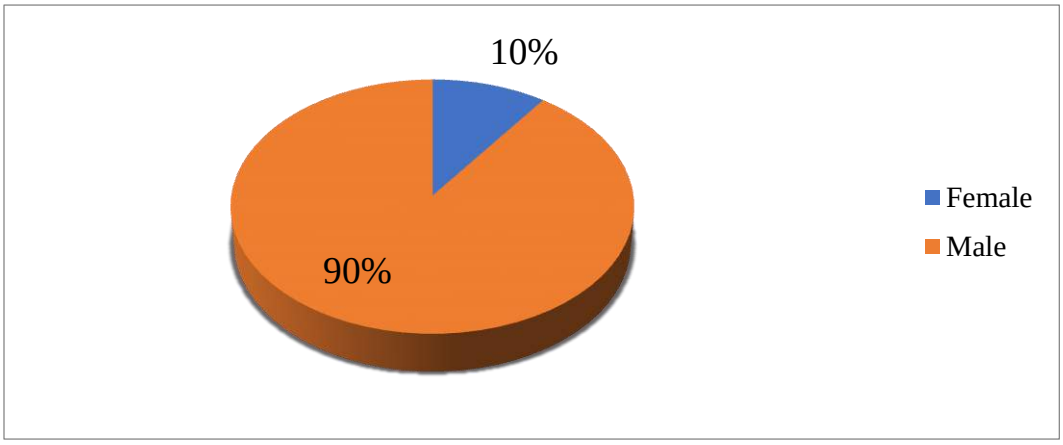


Figure 3 Shows distribution of patients in Group A according to Gender

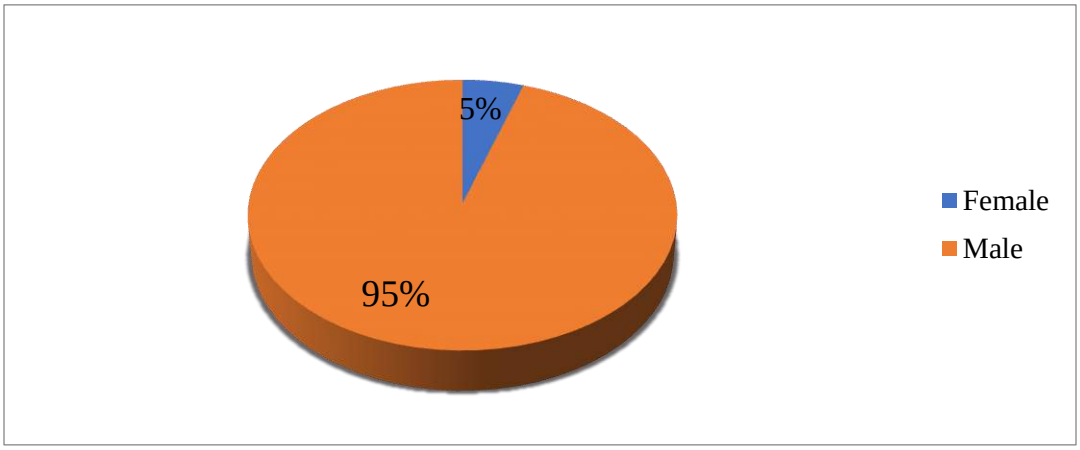


Figure 4 Shows distribution of patients in Group B according to Gender

3. Cause of injury

Road traffic accident (RTA) was the most common cause of injury in both the groups (80% in Group A; 85% in Group B). Fall from height accounted for 15% cases in Group A and 10% cases in Group B whereas assault was seen as a cause of injury in only 1 (5%) case in both the groups as depicted in Table 3.

Patient distribution according to cause of injury		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Cause of injury	RTA	16	80%	17	85%	33	0.230	0.891
	Assault	1	5%	1	5%	2		
	Fall	3	15%	2	10%	5		
Total		20	100%	20	100%	40		

Table 3 Shows distribution of patients in Group A and Group B according to cause of injury

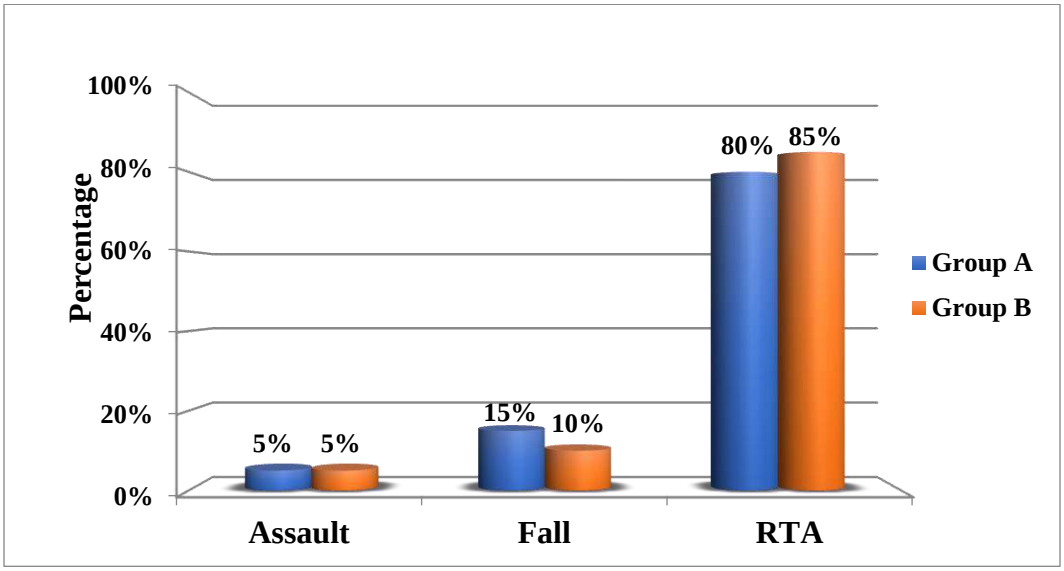


Figure 5 Shows distribution of patients in Group A and Group B according to cause of injury

Among the cases due to Road traffic accidents, most were associated with Two- wheelers in both the groups (11 cases in group A; 10 cases in group B). Four wheelers where involved in 4 cases in group A (20%) and 5 cases in group B (25%) (Table 4). 10 out of 15 patients involved in RTA were drivers in group A with 5 travelling in passenger seats, while 11 out of 15 patients were drivers in Group B with 4 travelling in passenger seats. While 1 patient in group A and 2 patients in group B were hit by a four-wheeler.

Patient distribution according to type of vehicle involved		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Type of Vehicle	Two Wheeler	11	55%	10	50%	21	0.635	0.888
	Four Wheeler	4	20%	5	25%	9		
	Hit by Four Wheeler	1	5%	2	10%	3		
	N/A	4	20%	3	15%	7		
	Total	20	100%	20	100%	40		

Table 4 Shows distribution of patients in Group A and Group B according to type of vehicle involved in RTA

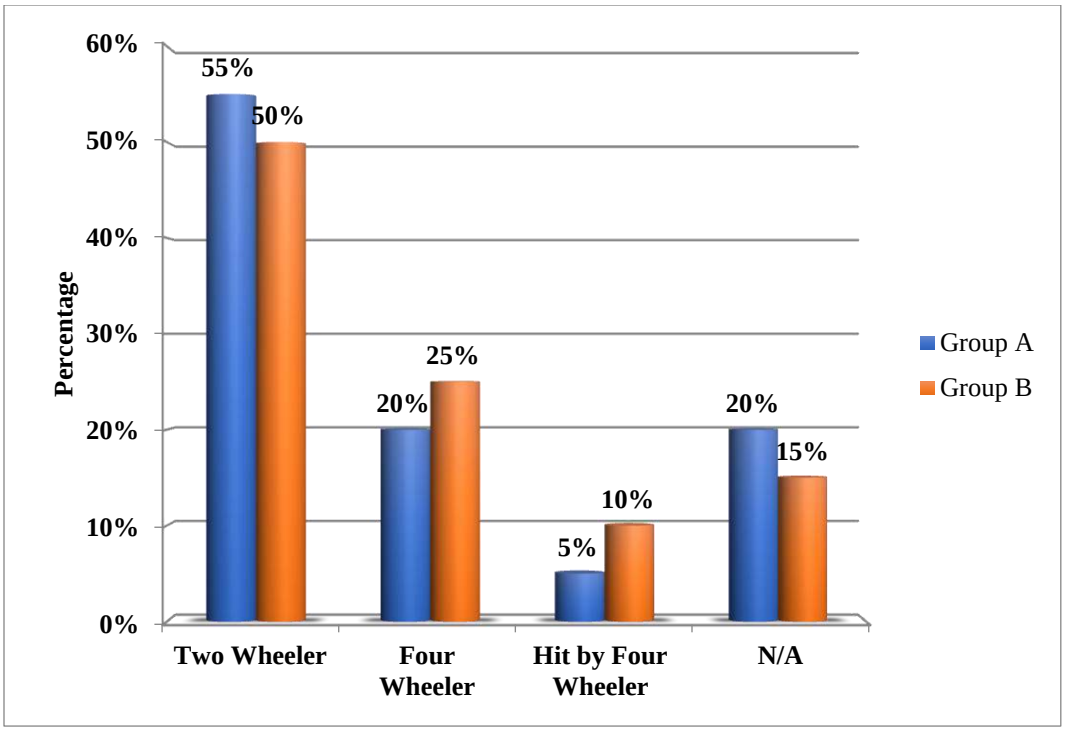


Figure 6 Shows distribution of patients in Group A and Group B according to type of vehicle involved in RTA

4. Preoperative Assessment

i. Periorbital edema- All patients (n=40) had periorbital edema on presentation out of which marked edema was seen in 9 (45%) cases in Group A and 6 (30%) cases in Group B.

ii. Subconjunctival haemorrhage- It was seen in 37 (92.5%) cases out of which 19 patients were in Group A and 18 patients were in Group B.

iii. Enophthalmos- In Group A, preoperative enophthalmos was present in 5 (25%) patients, while 6 (30%) had no enophthalmos and was not assessable in the remaining 9 (45%) patients due to marked periorbital edema. In Group B, preoperative enophthalmos was present in 9 (45%) patients, while 5 (25%) patients had no enophthalmos and it was not assessable in 6 (30%) patients.

iv. Telecanthus- It was seen in 4 (20%) patients each in both the groups.

v. Diplopia - It was present in total of 11 patients (5 in group A; 6 in group B), absent in 14 patients (6 in Group A; 8 in Group B) and was not assessable in 15 patients (9 in group A; 6 in group B) due to marked edema, unconsciousness or unresponsiveness of patients.

vi. Restricted ocular motility (ROM) - Restriction of ocular movement in upward gaze was seen in 4 (20%) patients in group A and 10 (50%) patients in group B, while it could not be assessed in 8 (40%) patients in group A and in 5 (25%) patients in group B.

vii. Infraorbital step deformity- 13 (65%) patients in Group A and 16 (80%) patients in Group B had Infra-orbital step deformity.

viii. Malocclusion-Malocclusion was seen in 10 (50%) patients each in both the groups.

These clinical findings have been summarized in Table 5.

Preoperative clinical findings		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Periorbital edema	Marked	9	45%	6	30%	15	0.960	0.327
	Mild	11	55%	14	70%	25		
Subconjunctival haemorrhage	Present	19	95%	18	90%	37	0.360	0.548
	Absent	1	5%	2	10%	3		
Enophthalmos	Present	5	25%	9	45%	14	1.834	0.400
	Not Assessable	9	45%	6	30%	15		
	Absent	6	30%	5	25%	11		
Telecanthus	Present	4	20%	4	20%	8	0.000	1.000
	Absent	16	80%	16	80%	32		
Diplopia	Present	5	25%	6	30%	11	0.977	0.614
	Not Assessable	9	45%	6	30%	15		
	Absent	6	30%	8	40%	14		
ROM	Upward Gaze	4	20%	10	50%	14	3.956	0.138
	Not Assessable	8	40%	5	25%	13		
	Absent	8	40%	5	25%	13		
Infra orbital step deformity	Present	13	65%	16	80%	29	2.910	0.233
	Not Assessable	0	0%	1	5%	1		
	Absent	7	35%	3	15%	10		
Malocclusion	Present	10	50%	10	50%	20	0.000	1.000
	Absent	10	50%	10	50%	20		

Table 5 Shows distribution of patients in Group A and Group B according to their preoperative clinical findings

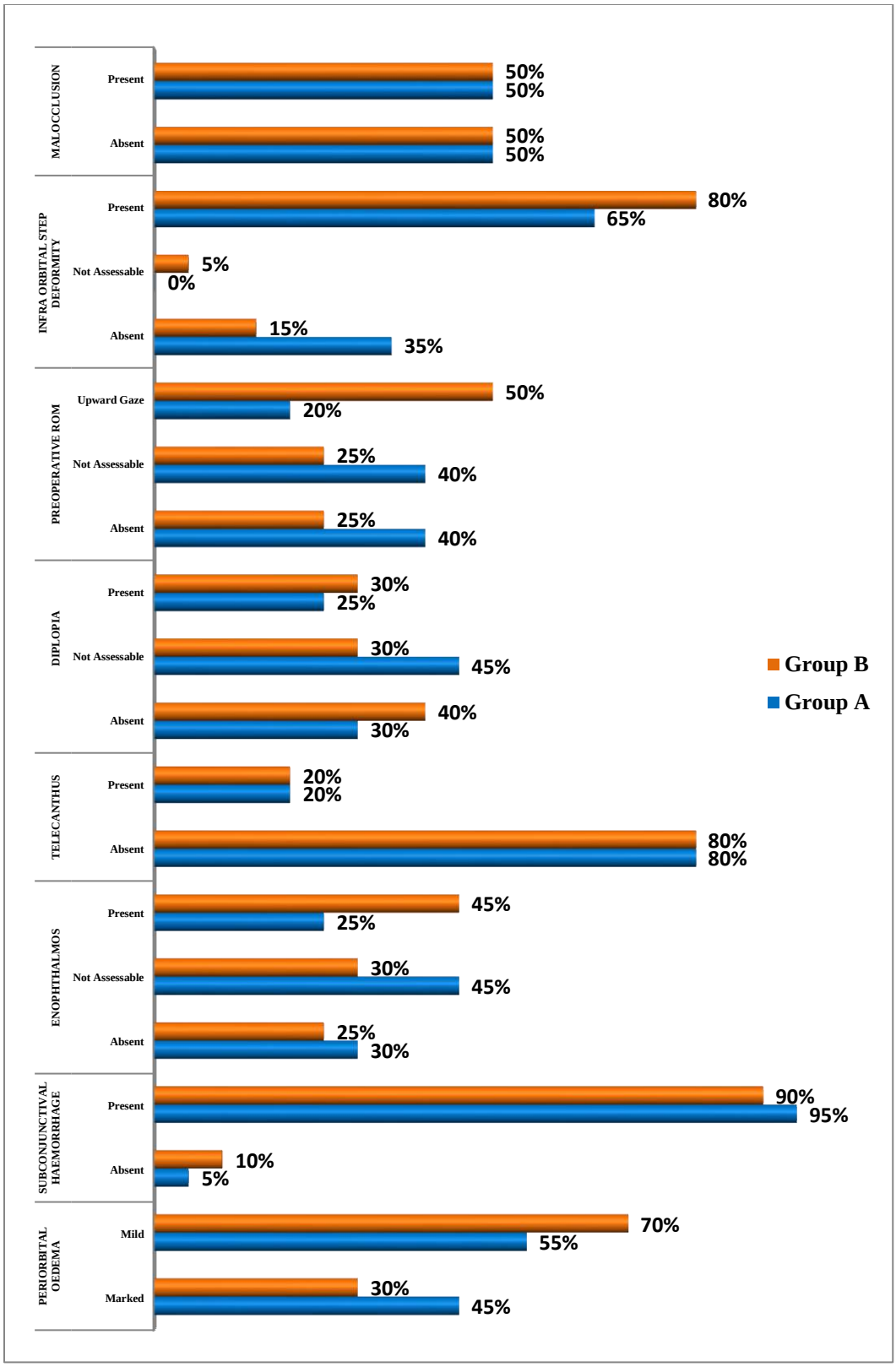


Figure 7 Shows distribution of patients in both the groups according to Preoperative clinical findings

5. 3D Reconstructed CT findings in Group A and CT with 3D Printed model findings in Group B

In Group A, CT face followed up by 3D reconstruction, orbital floor fracture involvement on left side was seen in 13 (65%) patients and on the right side in 7 (35%) patients. Fat herniation through defect was seen in 13 (65%) patients. Inferior rectus entrapment was noticed in 16 (65%) patients. Associated inferior orbital rim fracture was seen in 12 (60%) patients whereas medial orbital wall fracture was seen in 5 (25%) patients.
In Group B, on initial evaluation with CT face followed by 3D printed model creation, we found orbital floor fracture involvement on the left side in 13 (65%) patients and on the right side in 7 (35%) patients. Fat herniation through defect was seen in 11(55%) of patients. Inferior rectus entrapment was seen in 17 patients (85%), Inferior orbital rim fracture was seen in 16(80%) of patients whereas medial orbital wall fracture was seen in 4 (20%) patients as described in Table 6.

Orbital fracture findings on CT		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Orbital floor fracture	Present (Right)	7	35%	7	35%	14	0.000	1.000
	Present (Left)	13	65%	13	65%	26		
Fat herniation through the defect	Present	13	65%	11	55%	24	0.417	0.519
	Nil	7	35%	9	45%	16		
IR entrapment	Present	16	80%	17	85%	33	0.173	0.677
	Nil	4	20%	3	15%	7		
IO rim fracture	Present	12	60%	16	80%	28	1.905	0.168
	Nil	8	40%	4	20%	12		
Medial orbital wall fracture	Present	5	25%	4	20%	9	0.143	0.705
	Nil	15	75%	16	80%	31		

Table 6 Shows distribution of patients in Group A and Group B according to the orbital fracture findings on CT

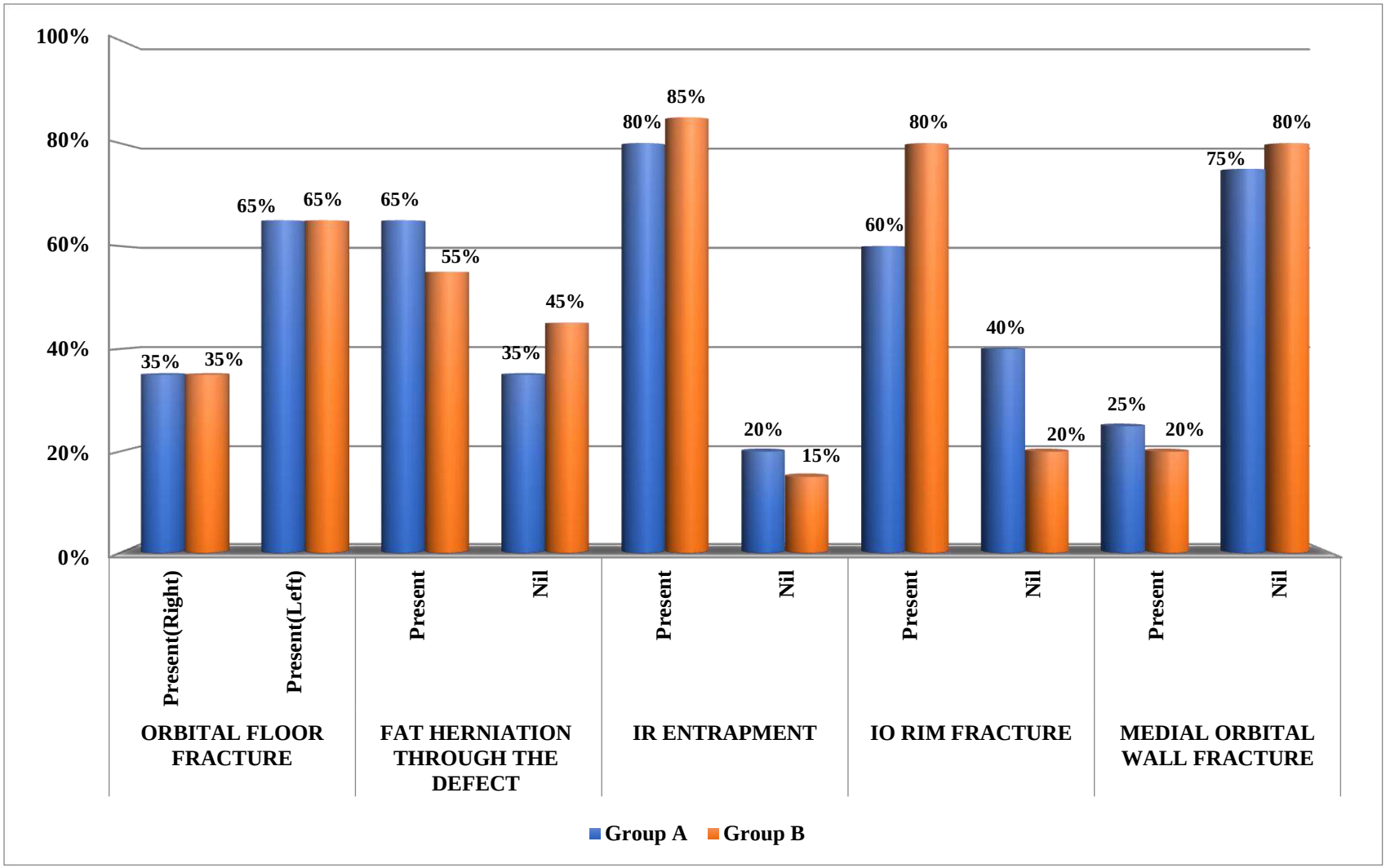


Figure 8 Shows distribution of patients in Group A and Group B according to the orbital wall fracture findings on CT

6. Associated fractures

In Group A, mandibular fractures were found in 6 (30%) patients (involving body in 2 patients, condyle in 1, parasymphyseal in 2 and ramus in 2). Maxillary fractures were found in 6 (30%) patients and nasal bone fractures were seen in 8 (40%) patients. Zygoma fractures were found in 11 (55%) patients.

In Group B, mandibular fractures were found in 8 patients (involving body in 1 patient, condyle in 2, parasymphyseal in 2 and ramus in 1). Maxillary fractures were seen in 11 (55%) patients and nasal bone fractures were seen in 11 (55%) patients. Zygoma fractures were found in 12 (60%) patients as shown in Table 7.

Associated Fractures		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Mandible fracture	Nil	14	70%	12	60%	26	1.487	0.829
	Present (Body)	2	10%	1	5%	3		
	Present (Condylar)	1	5%	2	10%	3		
	Present (PS)	2	10%	4	20%	6		
	Present (Ramus)	1	5%	1	5%	2		
Maxilla fracture	Present	6	30%	11	55%	17	2.558	0.110
	Nil	14	70%	9	45%	23		
Nasal bone fracture	Present	8	40%	11	55%	19	0.902	0.342
	Nil	12	60%	9	45%	21		
Zygoma fracture	Present	11	55%	12	60%	22	0.102	0.749
	Nil	9	45%	8	40%	17		
Total		20	100%	20	100%	40		

Table 7 Shows distribution of patients in Group A and Group B according to their associated fractures

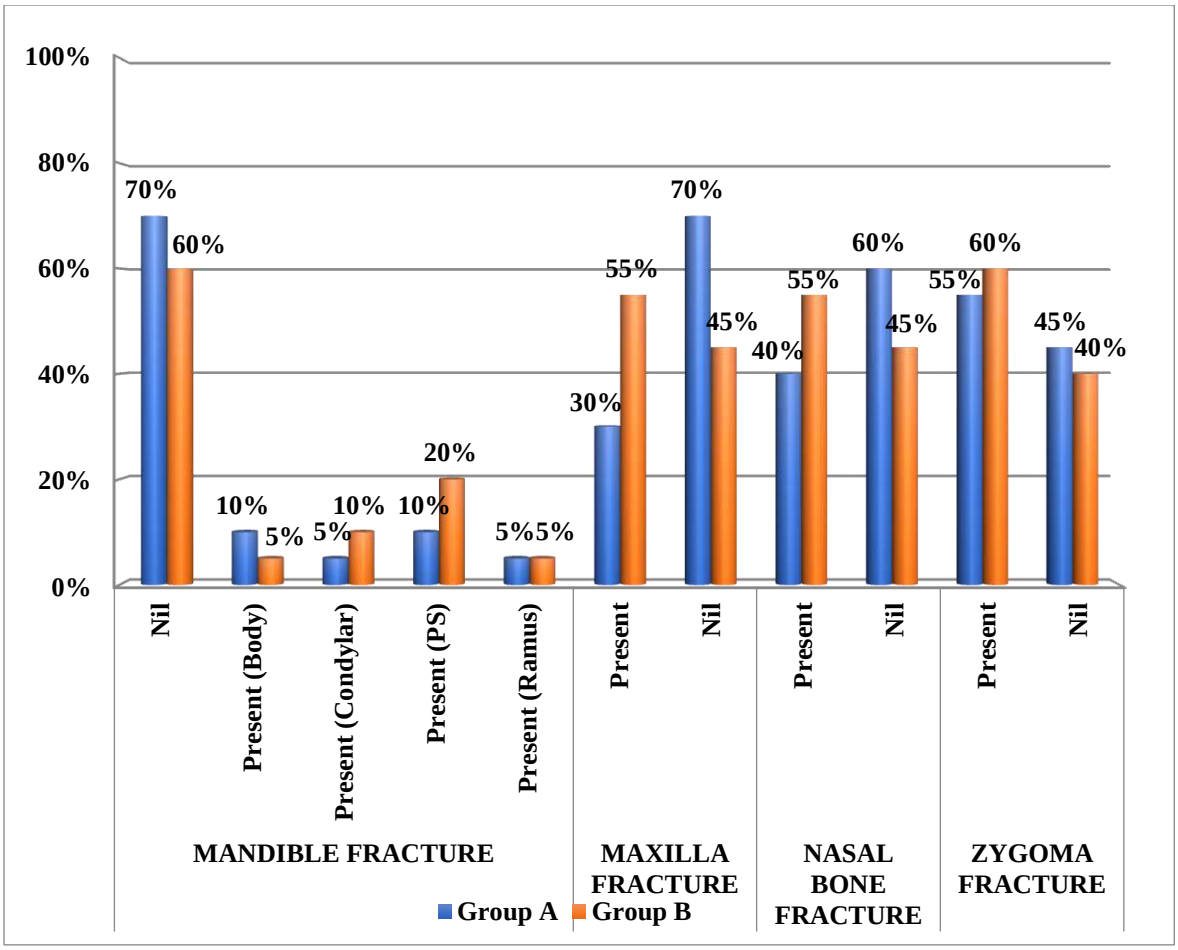


Figure 9 Shows distribution of patients in Group A and Group B according to their associated fractures

7. Defect Size of orbital floor

In Group A, mean defect size of orbital floor evaluated using 3D CT was 4.64 ± 0.94 cm^2 wherein the mean Max AP length was 2.68 ± 0.42 cm; and mean Max ML length was 1.78 ± 0.21 cm.

In Group B, mean defect size of orbital floor evaluated using 3D printed model was 4.93 ± 1.01 cm^2 with mean Max AP length of 2.70 ± 0.45 cm and mean Max ML length of 1.82 ± 0.19 cm. (Table 8)

The maximum defect size in group A was 6.60 cm^2 and that in group B was 6.30 cm^2 which was comparable. The minimum defect size was 2.85 cm^2 in each group.

Defect size	Group A (On 3D CT)	Group B (3D Printed model)	t	p-value
	Mean ± SD	Mean ± SD		
Max AP in cm	2.68 ± 0.42	2.70 ± 0.45	-0.183	0.856
Max ML in cm	1.78 ± 0.21	1.82 ± 0.19	-0.714	0.480
Defect size in cm^2	4.64 ± 0.94	4.93 ±1.01	-0.943	0.352

Table 8 Shows mean defect size in patients of Group A and Group B

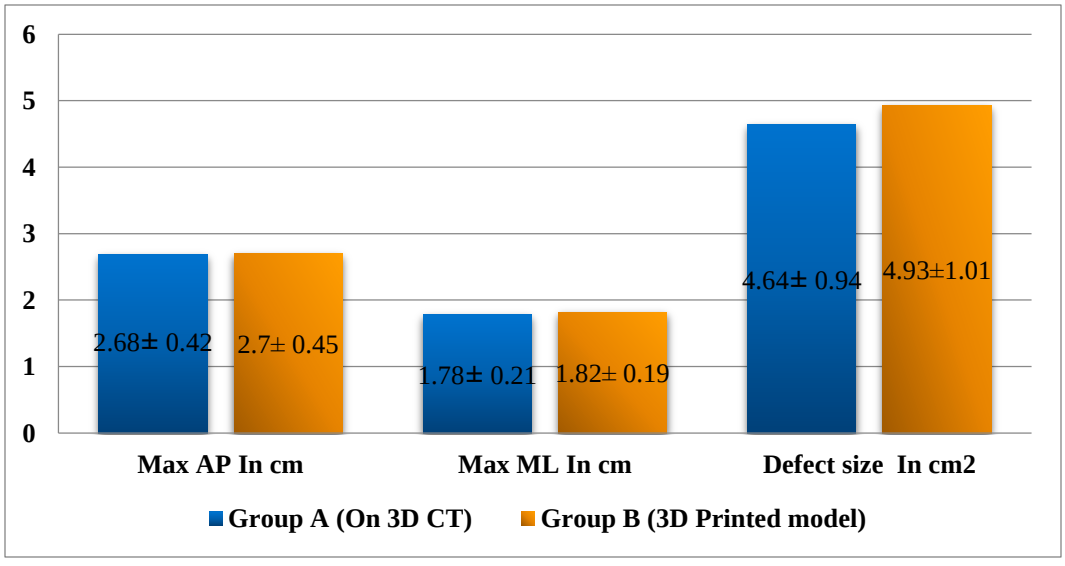


Figure 10 Shows mean defect size in patients of Group A and Group B

8. Preoperative understanding of injuries

Preoperative understanding score of injuries for which patient is going to undertake the surgery was fair in 18 (90%) cases and good in 2 (10%) cases in Group A. While in Group B, preoperative understanding score was fair in only 1 (5%) case and good in 19 (95%)cases as depicted in Table 9.We found Preoperative understanding was significantly higher in Group B cases when compared with Group A with a mean score of 9.30± 0.92 vs. 5.65±1.42 (p value =0.001;t-9.616).

Preoperative understanding	Group A		Group B		Total	Chi-square value	p-value
	No. of cases	%age	No. of cases	%age			
Poor (0-3)	0	0%	0	0%	0	28.972	0.001
Fair (4-7)	18	90%	1	5%	19		
Good (8-10)	2	10%	19	95%	21		
Total	20	100%	20	100%	40		

Table 9 Shows distribution of patients in both the groups according to their preoperative understanding of injuries

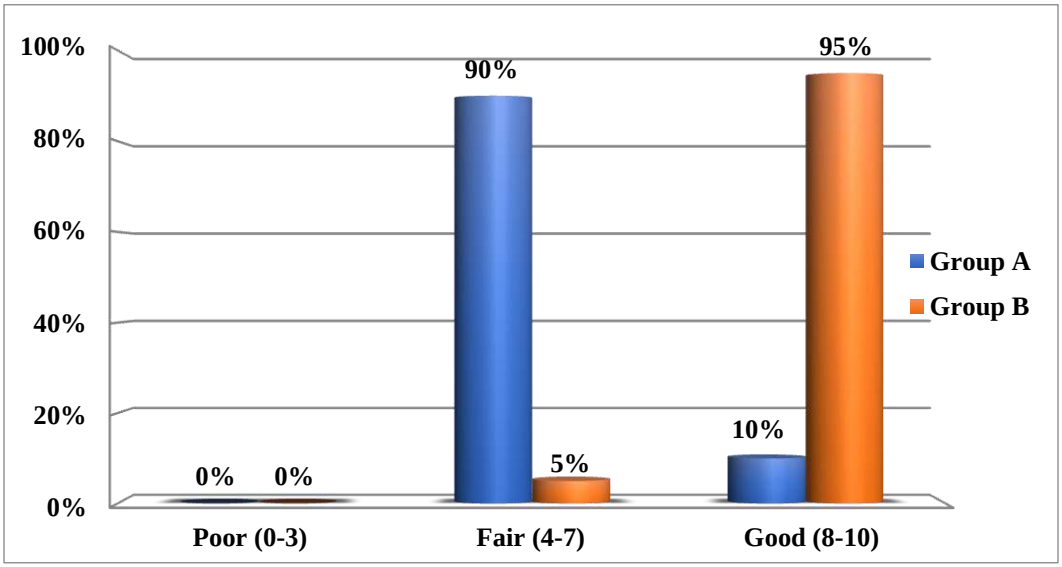


Figure 11 Shows distribution of patients in both the groups according to their preoperative understanding of injuries

9. Intraoperative parameters

Time elapsed from trauma to surgery was significantly lower in Group A when compared to Group B [1.45 ± 0.51 days vs. 5.55 ± 1.47 days; (p value = 0.001)] with maximum time elapsed in Group B being 8 days and in group A being 2 days.

Mean duration for orbital floor fracture fixation in Group A was 17.35 ±4.40 minutes and that in Group B was 6.30 ± 1.84 minutes, which was statistically significant with p value <0.001.

Among the 20 patients in Group B, a part of the plate was trimmed to fit the fracture site snugly in 17 cases along with bending of the plate which was needed in all cases to contour them preoperatively. Intraoperatively, maximum number of additional bends in Group A were 3 which were needed in 2 patients, 2 additional bends were needed in 9 patients and 1 in 7 patients and only in 5 patients the plate had to be trimmed after trying to manipulate it once to fit the fracture site.

While in Group B there was only one case in which 1 additional bend was required along with the need to cut 0.9 cm of the plate obliquely along its medial most part since the patient also had an associated medial orbital wall fracture as depicted in Table 10. No additional bends or trimming of the plate was required in the remaining cases.

Intraoperative Parameters	Group A	Group B	t value / Chi-square value	p value
Mean duration for orbital floor fracture fixation (min.)	17.35 ± 4.40	6.30 ± 1.84	10.355	0.001
Mean no. of additional bends to plates	1.55 ± 0.83	0.05 ± 0.22	7.843	0.001
No. of cases in which additional trimming of the plate was required intraoperatively	5 (25%)	1 (5%)	3.137	0.076

Table 10 Shows intraoperative parameters in patients of both the groups

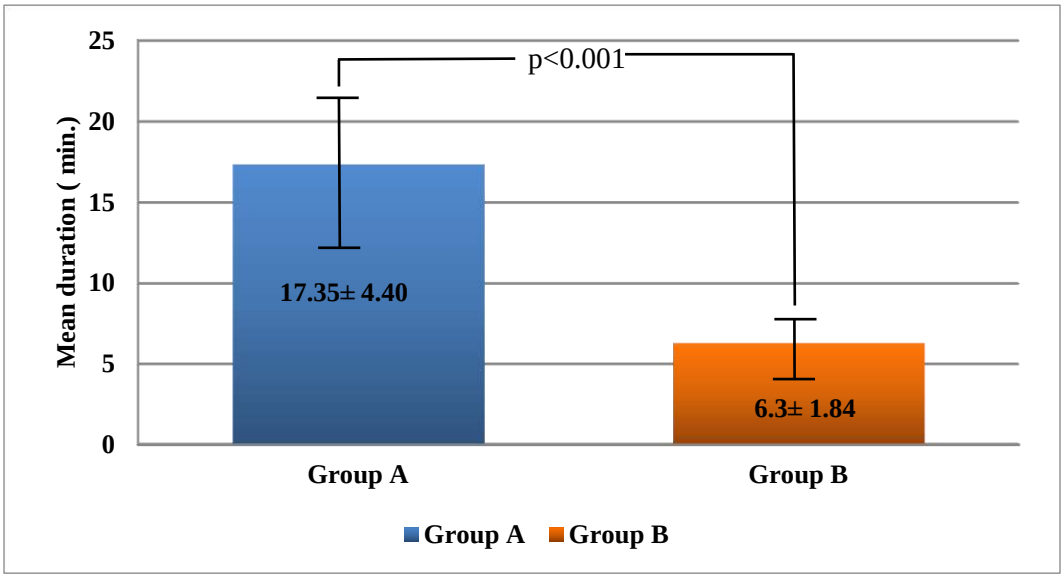


Figure 12 Shows mean duration for orbital floor fracture fixation in patients in both the groups

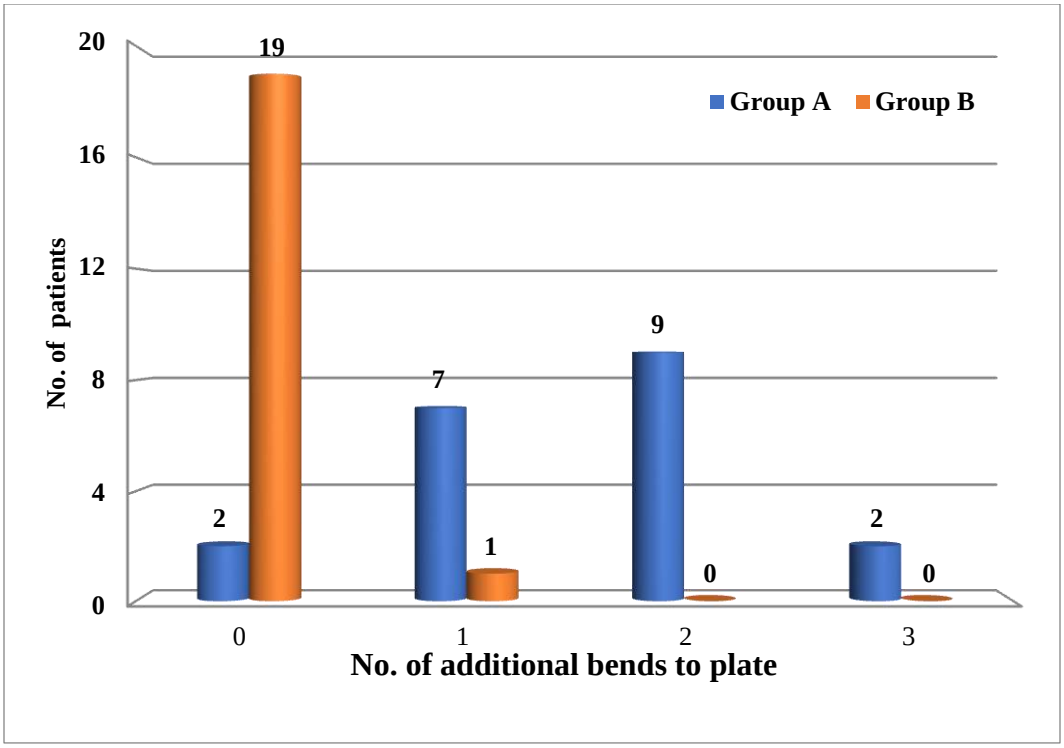


Figure 13 Shows distribution of patients according to number of additional bends to plate needed intraoperatively

10. Postoperative complications

i) There were no immediate plate related complications in either of the groups. 3 patients in Group A and 5 patients in Group B had anesthesia related complications like nausea, vomiting and sore throat.

ii) Enophthalmos

Enophthalmos was assessed at one week post operatively and was found in 4 (20%) patients in Group A and 3 (15%) patients in Group B. On follow-up after 4 weeks was found in 3 (15%) patients in Group A and 1 (5%) patient in Group B. These were the patients which had enophthalmos preoperatively and did not resolve completely.

iii) Telecanthus

Telecanthus was found in 4 (20%) patients in both the groups in immediate postoperative period all of them had telecanthus preoperatively as well and was seen in 3 (15%) patients in Group A and in 2 patients in Group B at one week follow up. It became clinically inapparent in all patients at 4 weeks.

iv) Diplopia

Diplopia was only present immediately after operation in 4 (20%) patients in Group A and 3 (15%) patients in Group B with none complaining of diplopia on follow up at 1 week and 4 weeks in both the groups.

v) Ocular movements

None of the patients in both the groups had any appreciable restriction of ocular movements immediately or at 1 week and 4 weeks of follow up.

vi) Occlusion

Patients with associated maxillary or mandibular fractures were repaired in 17 (85%) patients of Group A and 15 (75%) patients of Group B when assessed immediately after operation. Patients in both the groups achieved satisfactory occlusion at 1 week after Maxillomandibular fixation (MMF)

vii) Ectropion

Two patients developed ectropion, 1 (5%) in Group A and 1 (5%) Group B. These 2 patients had extensive soft tissue degloving injury at presentation. (Table 11)

Post operative complications		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Immediatepost operative								
Anaesthesia related (if/ any)	Present	3	15%	5	25%	8	5.458	0.243
	Nil	17	85%	15	75%	32		
Prosthesis related (if/ any)	Nil	20	100%	20	100%	40		
Facial contour symmetry	Not assessable	20	100%	20	100%	40		
Enophthalmos								
One week	Present	4	20%	3	15%	7	0.173	0.677
	Nil	16	80%	17	85%	33		
4 weeks	Present	3	15%	1	5%	4	1.111	0.292
	Nil	17	85%	19	95%	36		
Telecanthus								
Immediate	Present	4	20%	4	20%	8	0.000	1.000
	Nil	16	80%	16	80%	32		
One week	Present	3	15%	2	10%	4	0.228	0.632
	Nil	17	85%	18	90%	36		
4 weeks	Nil	20	100%	20	100%	40		

Occular movements								
Immediate	Normal	20	100%	20	100%	40		
One week	Normal	20	100%	20	100%	40		
4 week	Normal	20	100%	20	100%	40		
Diplopia								
Immediate	Present	4	20%	3	15%	7	0.173	0.677
	Nil	16	80%	17	85%	33		
One week	Nil	20	100%	20	100%	40		
4 weeks	Nil	20	100%	20	100%	40		
Occlusion (maxillary/ mandibular fractures):								
Immediate	Satisfactory	17	85%	15	75%	32	0.625	0.429
	Not Satisfactory	3	15%	5	25%	8		
One week	Satisfactory	20	100%	20	100%	40	0.000	1.000
4 weeks	Satisfactory	20	100%	20	100%	40		
Ectropion								
Immediate	Present	1	5%	1	5%	2	0.000	1.000
	Nil	19	95%	19	95%	38		
One week	Present	1	5%	1	5%	2	0.000	1.000
	Nil	19	95%	19	95%	38		
4 weeks	Present	1	5%	1	5%	2	0.000	1.000
	Nil	19	95%	19	95%	38		
Total		20	100%	20	100%	40		

Table 11 Shows distribution of patients according to postoperative complications in both the groups

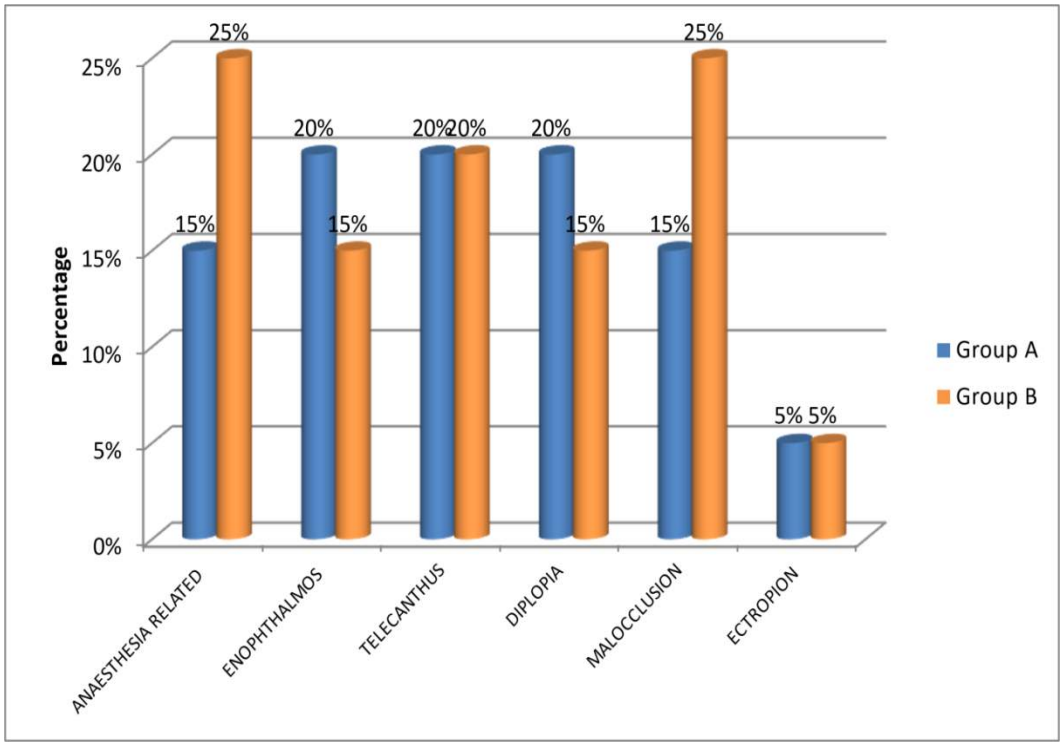


Figure 14 Shows distribution of patients according to immediate postoperative complications in both the groups

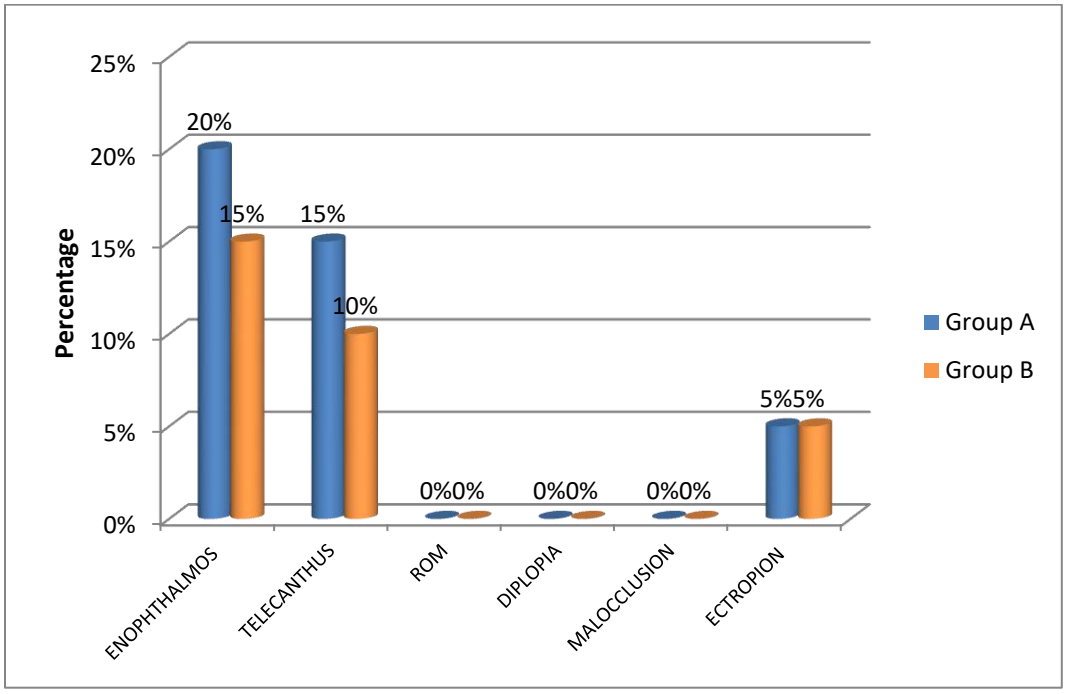


Figure 15 Shows distribution of patients according to postoperative complications at 1 week in both the groups

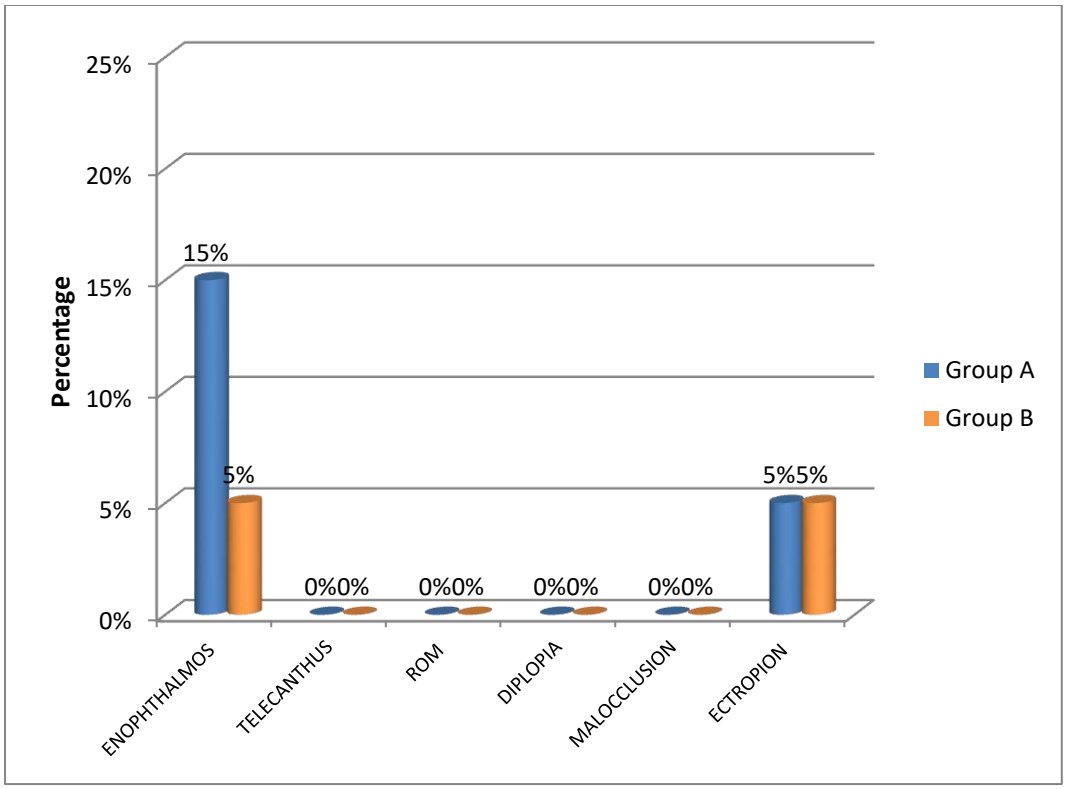


Figure 16 Shows distribution of patients according to postoperative complications at 4 weeks in both the groups

11. Facial edema

In Group A, on immediate evaluation post operatively, 10 (50%) patients had marked edema and 10 (50%) patients had mild edema whereas in Group B only 3 (15%) patients had marked edema and 17 (85%) patients had mild edema. This edema subsequently resolved as evaluated after 1 week of follow up, with only 10 (50%) patients in Group A and 4 (20%) patients in Group B having mild edema, which further resolved at 4 weeks of follow up with only 2 (10%) patients in Group A and 1 (5%) patient in Group B having only mild edema as depicted in Table 12.

Facial edema		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
immediate	Marked	10	50%	3	15%	13	9.979	0.001
	Mild	10	50%	17	85%	27		
1 week	Mild	10	50%	4	20%	14	3.956	0.046
	Nil	10	50%	16	80%	26		
4 weeks	Mild	2	10%	1	5%	3	0.360	0.548
	Nil	18	90%	19	95%	37		

Table 12 Shows distribution of patients according to postoperative edema in both the groups

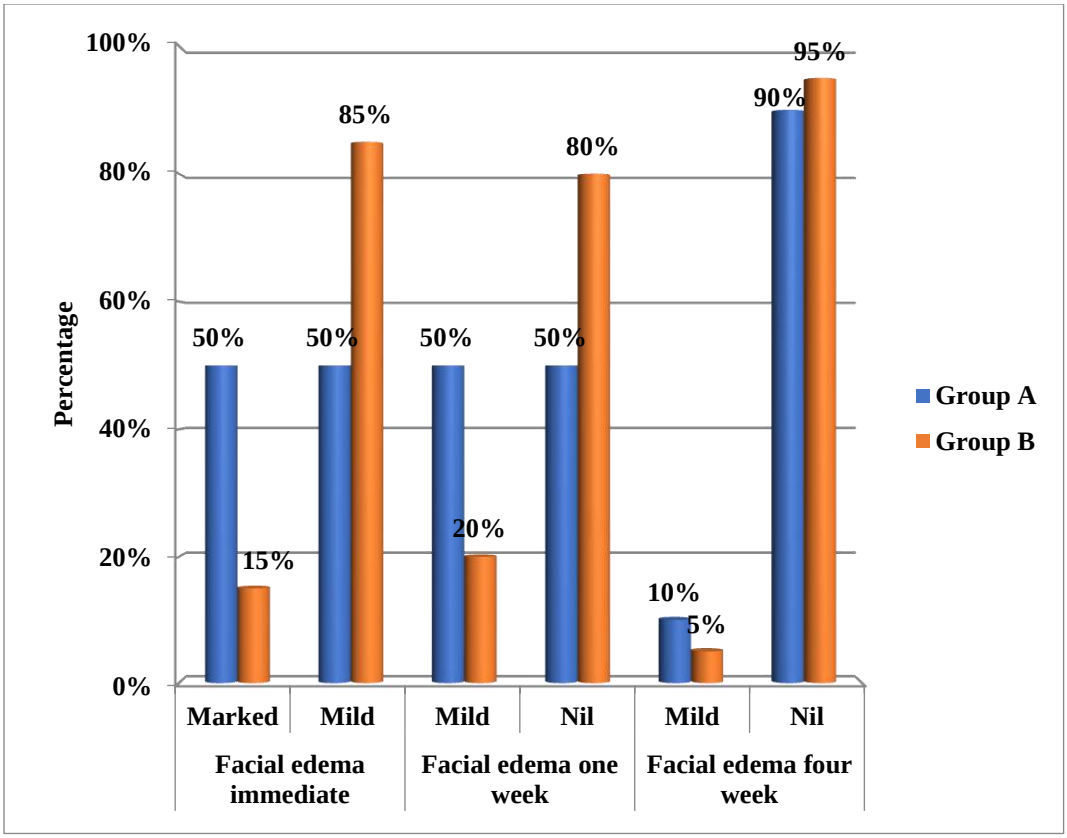


Figure 17 Shows distribution of patients according to post-operative edema in both the groups

12. Facial contour symmetry

Facial contour symmetry was not assessable in both groups immediately due to mild to marked edema. On 1weeks follow up, 8 (40%) patients in Group A and 2 (10%) patients in Group B had an asymmetrical facial contour which was statistically significant. (p-value=0.028) At 4 weeks of follow-up none of the patients had asymmetry in either of the groups as depicted in Table 13

Facial contour symmetry		Group A		Group B		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
1 week	Asymmetrical	8	40%	2	10%	10	4.8	0.028
	Symmetrical	12	60%	18	90%	30		
4 weeks	Symmetrical	20	100%	20	100%	40		

Table 13 Shows distribution of patients according to facial contour symmetry assessment in both the groups

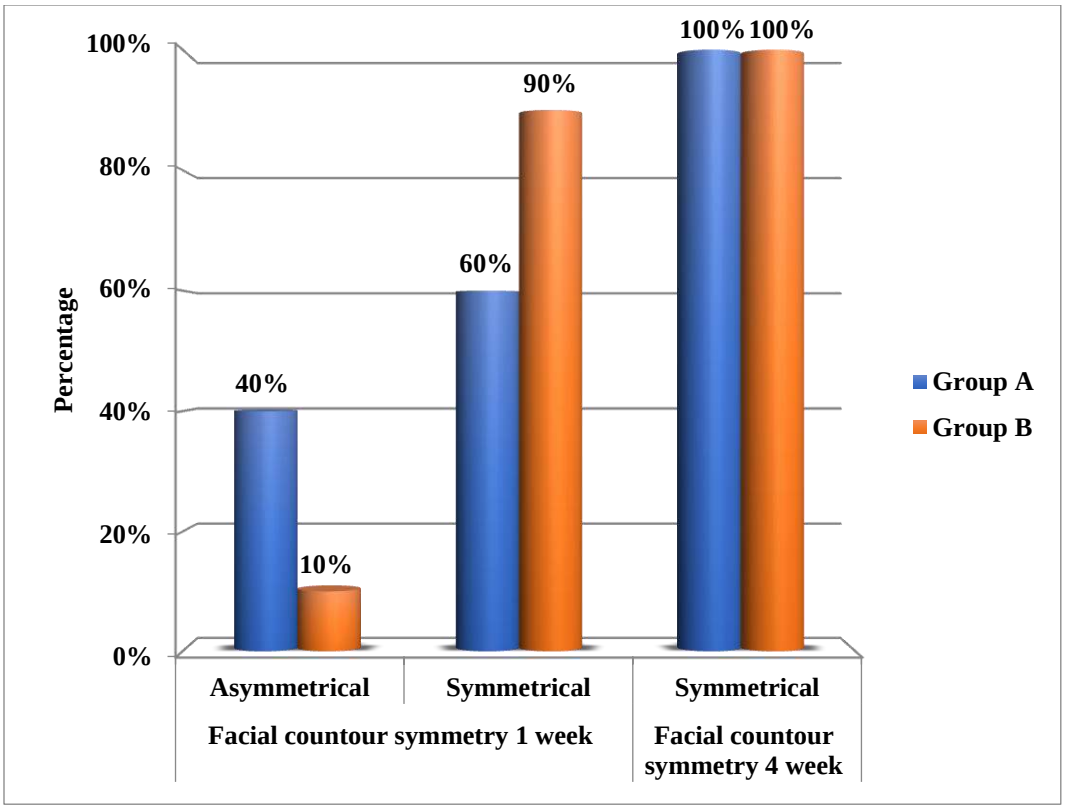


Figure 18 Shows distribution of patients according to facial contour symmetry assessment in both the groups

13. Patient Satisfaction

Patient satisfaction functionally and aesthetically was significantly better in Group B at 1 week and 4 weeks of follow up (p value = 0.012 and p value<0.001 respectively) when compared to Group A as depicted in Table 14.

In Group A, at 1 week of follow up, only 1 (5%) patient was highly satisfied, 14 (70%) patients were just satisfied and 5 (25%) patients were not satisfied. At 4 weeks, 4 (20%) patients were highly satisfied, 12 (60%) patients were satisfied and 4(20%) were not satisfied.

However, In Group B, at 1 week of follow up 9 (45%) patients were already highly satisfied, 9 (45%) patients were satisfied with the outcomes and 2 (10%) were not satisfied. At 4 weeks, 17 (85%) patients were highly satisfied, 2 (10%) patients were satisfied and 1(5%) was not satisfied.

Patient Satisfaction		Group A		Group B		Total	Chi-square value	p-value
Duration	Level	No. of cases	%age	No. of cases	%age			
1 week	Highly satisfied (8-10)	1	5%	9	45%	10	8.773	0.012
	Satisfied (4-7)	14	70%	9	45%	23		
	Not Satisfied (0-3)	5	25%	2	10%	7		
4 weeks	Highly satisfied (8-10)	4	20%	17	85%	21	108.26	0.001
	Satisfied (4-7)	12	60%	2	10%	14		
	Not satisfied (0-3)	4	20%	1	5%	5		

Table 14 Shows distribution of patients according to the level of patient satisfaction in both the groups

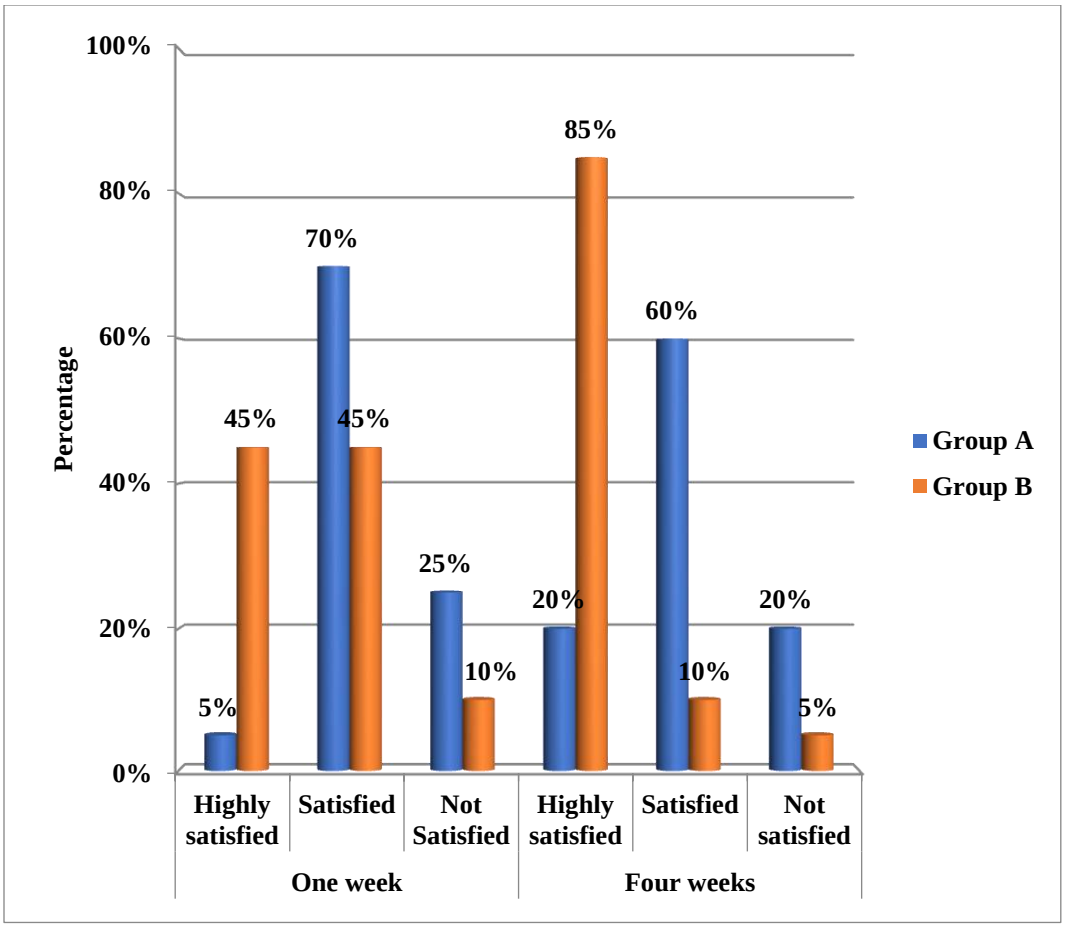


Figure 19 Shows distribution of patients according to level of the patient satisfaction in both the groups

DISCUSSION

The present prospective study was conducted at Dayanand Medical College and Hospital Ludhiana, involving 40 patients with facial fractures who were divided into 2 Groups of 20 patients each. The study evaluated and compared preoperative understanding, functional and clinical outcome, complications, and patient satisfaction levels after fixation of comminuted facial fractures between 2 groups: Group A where 3D CT scan was done and fixation plates were bent/cut intraoperatively as per the fracture and Group B where 3D printed models were made and using them as templates, the plates were preoperatively bent/cut, resterilised and then used for fracture fixation.

Patients in our study had comminuted fractures particularly involving the orbital floor. During our study we did not encounter any patient with comminuted mandible fracture who fulfilled the inclusion criteria for enrolment in Group B.

The mean age of all patients in our study was 31.07 ± 12.16 years. Majority of the patients in our study were in the age group of less than 30 years (19 out of 40; 47.5%) with 13 (65%)cases in Group A being in the age group of 31-50 and 13 (65%) cases in Group B being in the age group of <30 years of age . Most studies are in concordance to this finding of facial fractures being more common among young and middle aged adults. Similar findings were noted in studies by Hwang K et al.[19] where the most common age group involved was third decade of life and Smith H et al.[18] where the median patient age was 45 years .A descriptive analysis by Philamazan A et al. [70] including 120 patients to describe epidemiological profile of orbital fractures in orbital trauma found that 58.33% affected by orbital fractures were of age 16-35 years. We believe that this is because young people are more prone to violence and psycho-socio economic urban conflicts with more restlessness and risk taking behaviours including traffic risks leading to motor vehicle accidents.

This study showed a high male predominance with a male to female ratio of approximately 12:1 (92.5%; 37 out of 40). A retrospective study of 391 patients with orbital bone fractures by Hwang K et al. [19] showed similar findings with 77.5% male predominance. Kaur J et al. [33] also observed a higher incidence of mid face fractures in males (80%) as compared to females in their study of 100 patients with maxillofacial trauma. Higher incidences of orbital floor fractures among males can be attributed to the fact that in a developing country like ours more males are involved in outdoor activities and are more prone to RTA.

Most common cause of injury in this study was Road traffic accidents (82.5%; 80% in Group A, 85% in Group B) followed by falls (12.5%;15% in Group A, 10% in Group B) and assault (5%; 5% in both Groups). Similar findings have been reported by various previous studies in the literature. A 5 year study by Motamedi MH et al. [71] involving 237 patients with maxillofacial fractures also revealed leading cause of facial trauma as motor vehicle accidents seen in 54% cases followed by falls in 20.3% and assaults in 9.7%. Gewalli F et al.[72] reported that road traffic accidents accounted for 55% of the injuries while falls account for 15% among 56 patients with orbital fractures. Philamazan A et al. [70] observed similar findings in which motor vehicle accident was the most common cause observed in 55.83% cases followed by fall in 26.67%, assault in 10.83%, occupational in 4.17% and sports related injury in 2.5%. Contrary to most studies, Hwang K et al.[19] in their study involving 2000 patients with facial fractures reported violent assault or non violent traumatic injuries (49.4%) as the commonest cause of injury followed by slip or fall (14.5%), road traffic accidents (14.5%) and sports and work related injuries in 11.3% and 7.6% respectively. In developing nations, bad maintenance of roads, poor driving skills, lack of enforcement of traffic rules and regulations such as the use of seat belts and helmets are probable reasons responsible for such injuries.

In our study, amongst motor vehicles involved in RTA most common were the two-wheelers (55% in Group A and 50% in Group B) followed by four-wheeler (20% in Group A and 25% in Group B). Similarly Pati D et al. [73] in their study including 52 patients with NOE fractures reported that RTA was the commonest cause of injury (69%) among which two wheeler accidents accounted for 69% cases followed by four wheelers in 22% cases. Two wheeler accidents are more common and more often lead to facial injuries. The probable explanation for this is that a large proportion of the population in India use two-wheelers as the primary mode of transport. High-speed imprudence and not using helmets can explain the high number of NOE fractures secondary to two-wheeler accidents. In our study among those travelling on two wheelers (21 cases), 15 were drivers similar to findings in the study by Pati D et al.[73] where among those travelling on two wheelers, 19 were drivers and 6 were pillion riders. This could be attributed to the fact that in cases of head on collisions the driver is more prone to trauma.

The baseline pre-operative clinical findings were peri-orbital edema (100%), subconjunctival haemorrhage (92.5%), diplopia (27.5%), enophthalmos (35%), ocular movement restriction (35%), telecanthus (20%) and malocclusion (50%) and did not significantly differ (P>0.05) between the two groups. Reason for these clinical findings was that all the patients included in our study had comminuted orbital floor fractures. Similarly, Philamazan A et al.[70] in their study, including 120 patients with orbital fractures found peri-orbital edema in all cases (100%), ecchymosis in 85.83%, diplopia in 10% and ocular movement restriction in 51.67%. The decision to observe a fracture or proceed with surgery is based on the clinical examination, radiological imaging, and assessment of the risk and benefit of either option. Although history taking and physical examination play a pivotal role for initial diagnosis and planning for further management in any facial trauma patient, one has to rely mostly on radiological investigations to decide upon the need for surgical

intervention . Additionally, immediately following trauma, a patient might be non responsive or uncooperative due to concomitant injuries or may experience increased swelling of the facial area that has undergone fracture, thereby limiting the examiner's ability to appreciate certain findings[74] like in this study where findings of diplopia and restriction of ocular movement was not assessable in 15 (37.5%) and 13 (32.5%) cases respectively due to the altered sensorium and enophthalmos could not be assessed in 15(37.5%) cases due to marked periorbital edema. We observed telecanthus in 4 (20%) cases in each group all of which had associated medial orbital wall fracture and majority of which were also associated with nasal bone fractures.

In this study, location of orbital fractures were not significantly different in either of the 2 groups. Left sided orbital floor fractures were more common than right sided orbital floor fractures among all the patients in our study, accounting for 65% orbital floor fractures in each group which was similar to findings in a study by Chiang E et al.[75] who found that left orbital fractures were more common than right orbital fractures. Though left sided fractures are more common in patients who sustain assault injuries as explained by Chiang E et al.[75] in their study based on their hypothesis of higher prevalence of right handed assailants who are more likely to strike the victim's left orbit, in our study assault was not the most common reason for orbital floor fractures.

CT findings associated with orbital floor fractures were fat herniation through defect (Group A-65%, Group B-55%), inferior rectus entrapment (Group A-65%, Group B-85%), medial orbital wall fracture (Group A-25%, Group B-20%) and inferior orbital rim fracture (Group A-60%, Group B-80%). Similarly, Philamazan A et al. [70] in their study involving 120 facial fracture patients encountered medial wall fracture in 35%, lateral wall in 52.5% , orbital floor in 40%, orbital roof in 35% , soft tissue entrapment in 5.8%, extra ocular muscle entrapment in 5.8%. Other associated fractures of face, in our study, included maxilla (Group A-30%, Group B-55%),

mandible (Group A-30%, Group B-40%), nasal bone (Group A-40%, Group B-55%), zygoma (Group A-55%, Group B-60%) which did not affect the overall outcome assessment in our study .

The results of this study suggest that the mean defect size area (paired t-test, P=0.182), maximum AP length (paired t-test, P=0.771), and maximum ML length (paired t-test, P=0.107) was comparable between the two groups at baseline. It was 4.64 ± 0.94 cm^2 in group A and 4.93 ± 0.94 cm^2 in Group B similar to findings in a study by Sigron GR et al.[76] where the mean defect size was 3.89 ± 1.35 cm^2 in 3D model group and 4.08 ± 1.37 cm^2 in conventional group. Similarly, Seifert et al. [77] in their study also observed that the average orbital wall defect size was 297.9 mm^2 (± 190.8 mm^2*).*

It has also been reported in the literature that defects ≥2 cm^2 in size can cause clinically significant enophthalmos and hence need surgical intervention.[78] In our study the maximum defect size was 6.60 cm^2 in Group A and 6.30 cm^2 in Group B while minimum defect size was 2.85 cm^2 in both the groups. Most surgeons estimate the defect area by multiplying the maximum width and length.[79,80] similar to as done in our study depending on maximum AP and maximum ML measurements taken based on CT scan in Group A and 3D printed models in Group B.

Apart from surgical planning, 3D printed models are effectively being used in patient education and communication where surgeons can better explain the pathoanatomy and the surgical procedure. In our study as well, preoperative understanding in the 3D printed model group was significantly better than the 3D CT group. We are of the opinion that patients/ attendants have a better understanding of the fractures via visual and tactile feedback using their own anatomical model. Many studies have evaluated preoperative patient understanding with 3D printed models using self made questionnaires by authors in various pathologies like glioma[81] and congenital heart disease.[82] As far as facial fractures are concerned, there are a few studies available in the literature who have laid

emphasis on the use of 3D printed physical models in enhancing patient education and understanding of the facial fractures.[39] However, unlike this study none of the studies have evaluated the preoperative understanding of facial fractures quantitatively. In this study we used a self devised scoring scale which graded the patient's understanding of their facial fractures into poor, fair and good. We are of the opinion that 3 D printed models are simple and promising tools that help patients to better understand their exact fracture, treatment options, risks involved with a potential to improve shared decision making. However one drawback of 3D printed models is that they can be emotionally confronting for the patient particularly in early phase of disease.

Since all the patients in Group B were unfit for surgery at presentation due to presence of concomitant life threatening injuries mostly neurosurgical or hemodynamic instability, so the time elapsed from trauma to surgery was significantly higher in Group B when compared to Group A. The mean time to surgery in Group B in our study was 6.30±1.84 days which was primarily the average time taken for the patient to become fit for surgery. This time gap causing delay in surgery was utilised for 3D printed model creation which involved capturing the anatomical scans, creating a virtual 3D prototype, 3D printing of the material layer by layer and finally delivery of the model to our institution. Orbital floor fracture model has an estimated printing time of 8-10 hrs including a post processing time for removal of supportive material and quarantine after sterilization, the total turnover time is around 3 days. Pang SSY et al.[39] also observed a similar turn over time of 3-5 days in their study. Similar findings were found in a study by Mustafa SF et al.[83] where the shortest achievable time from injury to completion of 3D model was 5 days. This enables 3D printed models to be used for semi -elective situations only.

The waiting time to surgery was significantly higher (paired t-test, P=0.001), fracture fixation time was significantly lower (paired t-test,

P=0.001) and additional bends needed were significantly less (paired t-test, P=0.001) in Group B as compared to Group A.

Fractures of the orbital floor may be associated with significant potential complications like diplopia, enophthalmos, and infraorbital and optical nerve injuries due to nearby structures like the eyeball, optic nerve, and extraocular muscles.[84] In our study, the rate of these complications did not significantly differ between the two groups. However, patient satisfaction levels at 4 weeks was significantly better (Chi-square tests, P=0.001) in Group B.

In an endeavour for more precise and safer surgery, innovative technologies like computer-assisted approaches have assumed a pivotal role in orbital fracture management in the last few years involving use of 3D printed models, patient specific implants and CT image guided real time navigation. Before the availability of patient specific 3D printed models, size and shape of defect of orbital floor blow out fracture was estimated from the two-dimensional CT scan images and with the small trans-conjunctival incision, the bony defect especially the posterior ledge was difficult to be visualized clearly during the operation. Sometimes the implant had to be repeatedly retrieved from the subperiosteal plane after insertion for trimming and moulding for more precise placement which could theoretically increase implant fatigue, increase soft tissue handling, worsen tissue edema and prolong operative time. The anatomical areas of the face such as orbit, which are difficult to access and have surface irregularities making moulding of implants difficult are ideal zones where prebent plates can be used using 3D printed models. We strongly believe, that with 3D printed skull model as guides, surgeons are able to predict how far the fixation plate can be inserted to achieve sufficient coverage of the defect even at the posterior aspect of the orbit without the fear of damage to optic nerve and ophthalmic vessels.

One of the main advantages of prebent plates based on 3D printed orbital models is the significant reduction of surgery time. Since most patients in

this study had multiple facial fractures, so the surgery time in our study was calculated specifically pertaining to the fracture site for which 3D printed model was made. This extended from the point of complete reduction of fracture to the point of insertion of the last screw for fixation of the plate. The surgical time in our study was in line with the results of other studies that found that individual planning decreases the operation time. We observed that the mean surgical time was significantly shorter in prebent implant Group B (6.3±1.8 min) versus Group A (17.3±4.4 min). A retrospective study by Sigron GR et al.[76] observed that prebent implants can significantly reduce operation time by 42.5 min as compared to intraoperative bending approach in isolated orbital floor fractures using standard titanium meshes. In their study the total surgery time extended from point of skin incision to end of skin closure since they were dealing with isolated orbital floor fractures. Another study by the same author reported significantly shortened surgical time by 35.9 min in the intervention group.[85] Lethaus B et al.[86] reported that prebent implants saves an average of 0.4 hours of operating time. Mustafa SF et al. [82] also noticed a decrease in surgical time from 93.3 min using standard plates to 48.3 min using prebent plates based on 3D printed models. Additionally short operative time can decrease intraoperative complications by reducing the time of general anaesthesia.

The 3-D printing technique appears to be of great value for predicting the precise fracture zone before and during surgery, and can help surgeons achieve accurate anatomical reconstruction for repairs of blowout orbital fractures. In a randomized controlled trial, Kende P et al. [87] compared the efficacy of prebent plating system employing 3D printing with conventional plating in the management of mandibular fractures. In group 1 (control group), plate was adapted and fixated conventionally to the fracture site while in group 2 (experimental group), prebent plate was adapted and fixated to the fracture site. The number of bends required, and duration of fracture fixation were significantly lower ($P<0.001$) in the experimental

group. Our study was in line with this study with significantly lower bends (0.05±0.2 versus 1.5±0.8) and duration (6.3±10.3 versus 17.3±4.4 min) between 3D printing group and control group, respectively.

Similar to our comparative study, Raisian S et al. [68] compared the efficacy of customized patient-specific titanium mesh based on 3D printed model with intraoperative bending of titanium mesh for reconstructing of orbital floor fracture. In conventional group (n=5), the titanium mesh was bended manually and intraoperatively by surgeon and positioned over the bony defect. All patients were followed-up within 1 week, 1 month and 4 months, respectively after surgery. Patients were assessed for enophthalmos, diplopia and other complications. The authors also reported that there was a significant difference in enophthalmos between the control and intervention groups at 4 months postoperatively (2.4±0.8 versus 0.35±0.4, P<0.001). In our study, 3(15%) patients in Group A and 1(5%) patient in group B had enophthalmos at 4 weeks postoperatively (Chi-square tests, P=0.292). The incidence of postoperative enophthalmos is not widely reported, and ranges from 7% to 27% in orbital fractures repaired by conventional implants and in patient-specific implants, it ranges from 0-25%.[88] Although enophthalmos may not lead to visual disturbance, it can result in unacceptable cosmesis. When enophthalmos is greater than 2mm, appearances may be viewed as abnormal, suggesting that enophthalmos is clinically significant. Most studies, however, did not report the degree of enophthalmos, or the degree of resolution postoperatively making comparisons difficult.[74,89]

In this study none of the patients had diplopia on long term follow up postoperatively. With conventional orbital fracture fixation, the reported rate of persistent diplopia ranges from 8% to 42% and 4-40% in prebent implants cases.[25] Kim YC et al. [67]also compared the prebent implant group with a conventional group. After a 3-month follow-up period, the rates of postoperative diplopia were recorded in 2 of 44 (5%) PSI cases compared with 5 of 38 (13%; p = 0.14) conventional cases (5% vs. 13%; p

= 0.14). However, variable results were reported in uncontrolled studies. Zhang X et al.[51] reported resolution of diplopia in 12 of 12 cases over a 25-month follow-up period. Park SW et al.[90]did not report the preoperative incidence of diplopia but noted persistent diplopia in 2 of 127 (2%) cases that required return to OR. A higher proportion of diplopia was observed by Dvoracek LA et al.[91] who reported persistent diplopia in 2 of 9 (22%) cases, and Mustafa SF et al.[83] who reported preoperative diplopia in 17 of 22 (77%) patients, and postoperative diplopia in 7 (32%) patients, although the follow-up period varied significantly from 2 to 38 months. The widely reported range in incidence makes it difficult to confidently conclude that prebent implants will produce lower rates of diplopia. When traditional implants are utilized, Hosal and Beatty[92] reported postoperative diplopia more likely in older patients, and in cases where repair was delayed.

Besides diplopia and enophthalmos, complications in orbital surgery include infection, incision related complication (ectropion) , implant migration and potentially, blindness. The incidence of these complications is not widely reported. [93] The incidence of postoperative blindness is limited to case studies and is thought to be related to retrobulbar haemorrhage producing a compartment syndrome. No case of blindness was seen in our study sample. We had no case of implant related complication, however we had 2 cases who developed ectropion post operatively, 1 in each group (5%), both these patients had extensive soft tissue degloving injury at the time of presentation. One of the two patients in Group B was reoperated after 3 months and underwent subcision with fat grafting to achieve better aesthetic outcome while the other patient who was in Group A showed regression of ectropion with time. Our findings were similar to a study by Sigron GR et al.[85], where no major complication such as retrobulbar hematoma occurred and ectropion was recorded in 2 cases each from the conventional bending group (total 17 patients) and 3D model based prebent plate group (total 13 patients) and

regressed over time. Among the 8 cases (4 in each group) who had telecanthus preoperatively in our study ,3 cases in Group A and 2 cases in Group B continued to have mild telecanthus even at 1 week follow up which could be attributed to postoperative edema. In all these case telecanthus clinically inapparent at 4 weeks .

Malocclusion was observed in 3 patients in immediate post operative period which was satisfactorily treated with maxillomandibular fixation .These were the cases that had associated maxillary or mandibular fractures apart from orbital floor fractures . Malocclusion though assessed post operatively ,in our study ,did not effect the final outcome.

Facial edema and facial contour asymmetry were significantly less among patients in Group B (prebent plates) as compared to patients in Group A (conventional intraoperatively bent plates) at 1 week postoperatively .We noticed an early resolution of post operative edema and improvement of facial contour symmetry in the group where 3D printed models were used . This could be attributed to enhanced accuracy of fixation and lesser tissue manipulation with precontoured plates.

Despite availability of several studies on facial fractures, an assessment of patient's satisfaction levels seem to be lacking. Most studies also lack a control group. Holtmann H et al. [94] evaluated contentedness in relation to foreign body sensation, diplopia, enophthalmos and exophthalmos and showed high contentedness in the cohort. In the retrospective study of Poeschl et al.[95], the complaint of one patient out of 60 regarding ectropion was noted but a general questionnaire was not performed. Another study assessed patient's complaints with a questionnaire and found difference between the perception of subjective discomfort and objective findings in the ophthalmologic verification.[96] The present study, however, found that patients were more satisfied with prebent implants at 4 weeks postoperatively.

Potential disadvantages of 3D printing included the additional cost, need for 3D software engineering expertise, and a lengthy turnaround time

making them impossible to receive the models in time for acute surgery.[57] Problems encountered with software bugs and printing failures also amount to a major limitation as far as use of 3 D print models is concerned. Resterilization of the prebent plate may add to the cost of surgery and is therefore another time and resource consuming process leading to further delay in surgery.[56] Additionally a range of unwanted artefacts that create distortions on medical models have been identified in a study by Winder J and Bibb R.[57] Though lengthy turnaround time for creation of 3D printed models was treated as a limitation of 3D printed models in various studies but in our study the time gap causing delay in surgery due to patient's unfitness for surgery was utilised for 3D printed model creation .

Computer designed Patient Specific Implants although offer a more accurate reconstruction of maxillofacial defects than 3D models, they do have few drawbacks like higher cost and longer manufacturing time. Hence, this technology is not widely used currently in developing countries. Despite the potential cost limitation, the price of 3D technology is continuing to be driven down in terms of the price of devices, materials and software.[58] The major limitations including time and cost, may be offset by decreased operating times and collaboration between departments to diffuse in-house printing costs.

Strengths of the study - There area very few studies available in the literature on the role of 3D printed models in facial fractures that are prospective in nature. Being a prospective study we could analyse the patients preoperatively, intraoperatively and postoperatively sequentially and evaluate the operative ease as well as postoperative outcomes in terms of resolution of preoperative clinical findings. Ours is a comparative study evaluating the role of 3D printed models vs 3D CT scan in the management of facial fractures. This is of particular value in a resource limited developing country like ours where an ascertained significant improvement of intraoperative fixation of facial fractures and postoperative

outcomes can propel the authorities to establish immediate printing of implants at the point -of-care. This study is among the very few studies that have laid emphasis on the need for patient education before the surgery regarding his/her injuries which leads to informed decision making. Moreover, most studies seem to lack patient satisfaction assessment in the postoperative period after the use of prebent plates or intraoperatively bent plates for facial fracture fixaton. This study evaluated the patient satisfaction objectively using a numeric scale.

Limitations of the study - The sample size was relatively small (n=20) limiting the statistical power of our analysis leading to a type II error and consequently overestimation. Also, patients were followed up for a short period of time (4 weeks). A much longer follow-up (>6 months) would have been better for concluding that the placement of pre bent plates for fixation of facial fractures actually led to favourable long term outcomes when compared to conventional manual bending. Another limitation of our study was that we did not do a postoperative radiological evaluation to assess precise placement of plates and also did not compare with the contralateral uninjured side regarding adequacy of fracture reduction and restoration of orbital volume.

We conclude that the use of 3D printed model is a promising tool for fixation and reconstruction of midfacial (orbital) fractures. The physical models provide a better insight into orbital anatomy and serve as a template for accurate prebending of the plate according to the complex surface undulations of the orbital floor defects. Additionally, the use of 3D printed model improves patient's understanding of their facial fractures significantly. In comparison to the conventional treatment of facial fractures with intraoperative manual bending of plates, the results of our present study shows that use of prebent plates: requires fewer additional intraoperative manipulations, lesser tissue manipulation, shortens operative time, leads to better fracture fixation and therefore, results in significantly better patient satisfaction levels postoperatively. Usage of 3D

printed models for prebending the plates was also associated with early resolution of facial edema and improvement of facial contour symmetry.

SUMMARY & CONCLUSION

Use of 3D printed models for preoperative planning and management of patients with facial fractures provides an integrated approach with better surgical and aesthetic outcomes.

This prospective comparative study was conducted at Dayanand Medical College and Hospital, Ludhiana, to evaluate and compare management outcome of facial fractures using either 3D printed model of injured area or 3D reconstructed CT.

A total of 40 patients with facial fractures were included in this study Group A included 20 patients who underwent 3D reconstructed CT followed by conventional method of fracture fixation using plates bent intraoperatively and Group B included 20 patients who were unfit for immediate surgery and underwent CT followed by creation of 3D printed model of the fractured segment which was used as a template to prebend the plate for fracture fixation. Data was collected and analyzed from preoperative assessment, patient understanding, intraoperative findings, postoperative assessment and patient's level of satisfaction. In both the groups, patients were followed up postoperatively and findings were noted in the immediate post operative period (within 24 hours), at one week and at four weeks.

We found a higher incidence of facial fractures among males (92.5%) and young population i.e.<30 years of age (47.5%) with road traffic accidents being most common cause of injury (82.5%), followed by fall (12.5%) and assault (5%).

Clinical features associated with mid-face injuries in our study were peri-orbital oedema (100%), subconjunctival hemorrhage (92.5%), enophthalmos (35%), diplopia (27.5%), restriction of ocular movements (35%), telecanthus (20%), infra-orbital step deformity(72.5%), malocclusion (50%).

Other associated orbital and mid-face fractures with orbital floor in our study were inferior orbital rim (70%), medial orbital wall (22.5%),

mandibular (35%), maxillary (57.5%), nasal bone (47.5%) and zygomatic fractures (55%).

3D printed model provides a better patient understanding about injury preoperatively when compared to 3D reconstructed CT [mean score of 9.30± 0.92 (Group B) vs 5.65±1.42(Group A) (p value =0.001; t-9.616)].

Patients surgically treated with prebent plates made using 3D printed model as template in Group B required comparatively less intraoperative time (6.30 ± 1.84 mins vs 17.35 ±4.40 mins; p value = 0.001), less intraoperative manipulations (mean number of additional bends being 0.05 ± 0.22 vs 1.55 ±0.83) and less additional intraoperative trimming of the fixation plate [needed in 1(5%) case vs 5(25%) cases] when compared to conventional intraoperative bending of plates in Group A.

Number of complications were less among patients treated with pre-bent plates using 3D printed model. Facial edema and facial contour asymmetry were significantly less among patients in Group B (3D printed model) postoperatively and at one week (p- value = 0.046,0.028 respectively)

Level of satisfaction was significantly higher among patients in Group B (3D printed Model) at one week (p value=0.012) and four weeks (p value=0.001) postoperatively.

CONCLUSION

This study concludes that preoperative bending of plates for fracture fixation using 3D printed models of injured area as template, when compared to conventional intraoperative bending of plate, has better clinical outcomes, decreases operative time, involves less intraoperative modifications of plate, decreases tissue manipulation and results in better fixation. 3D printed model also has an additional benefit of better patient understanding and education of the injury. Surgical correction using prebent plates based on 3D printed models results in better level of patient satisfaction with early resolution of facial edema and improvement of facial contour symmetry when compared to conventional method.

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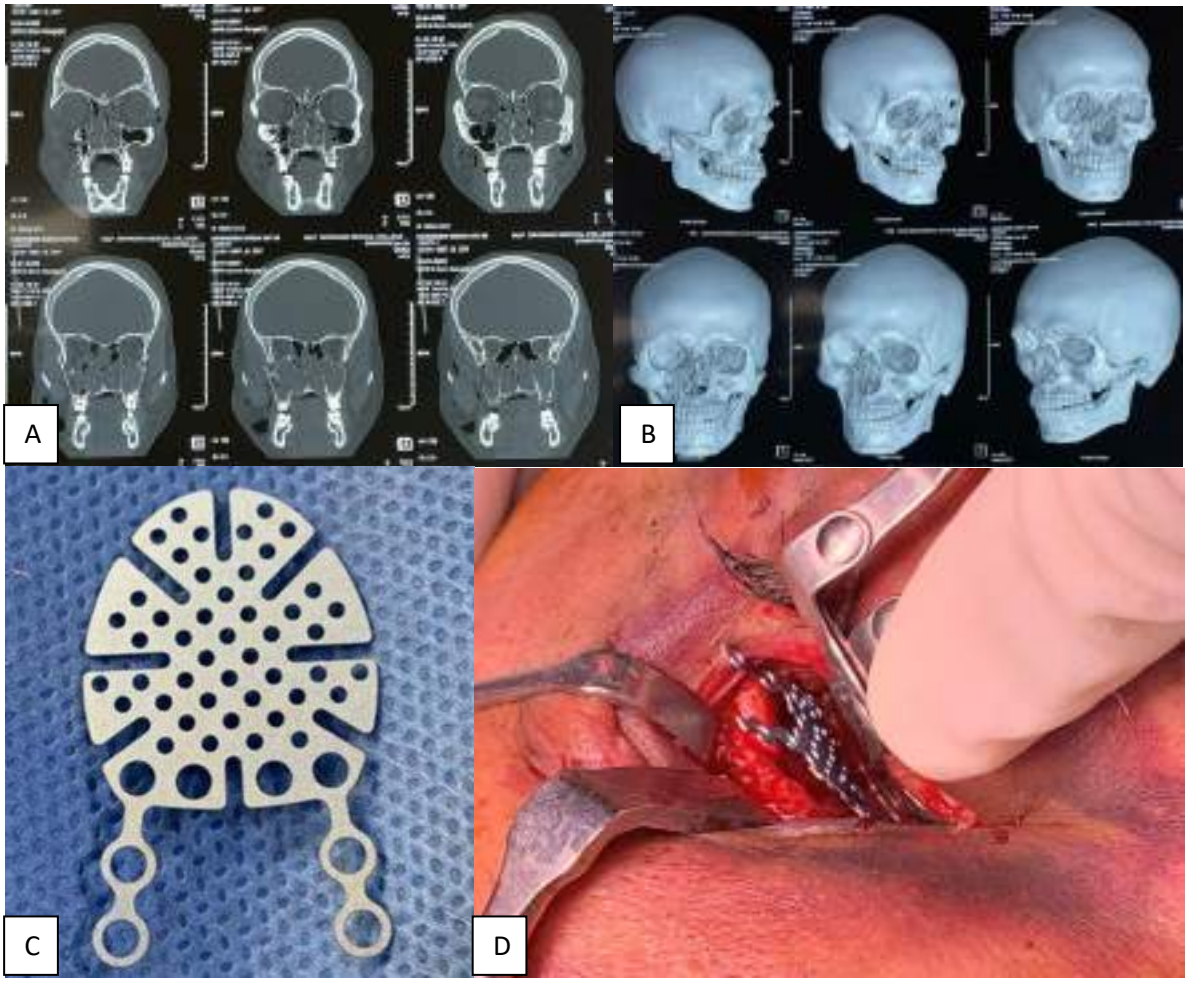
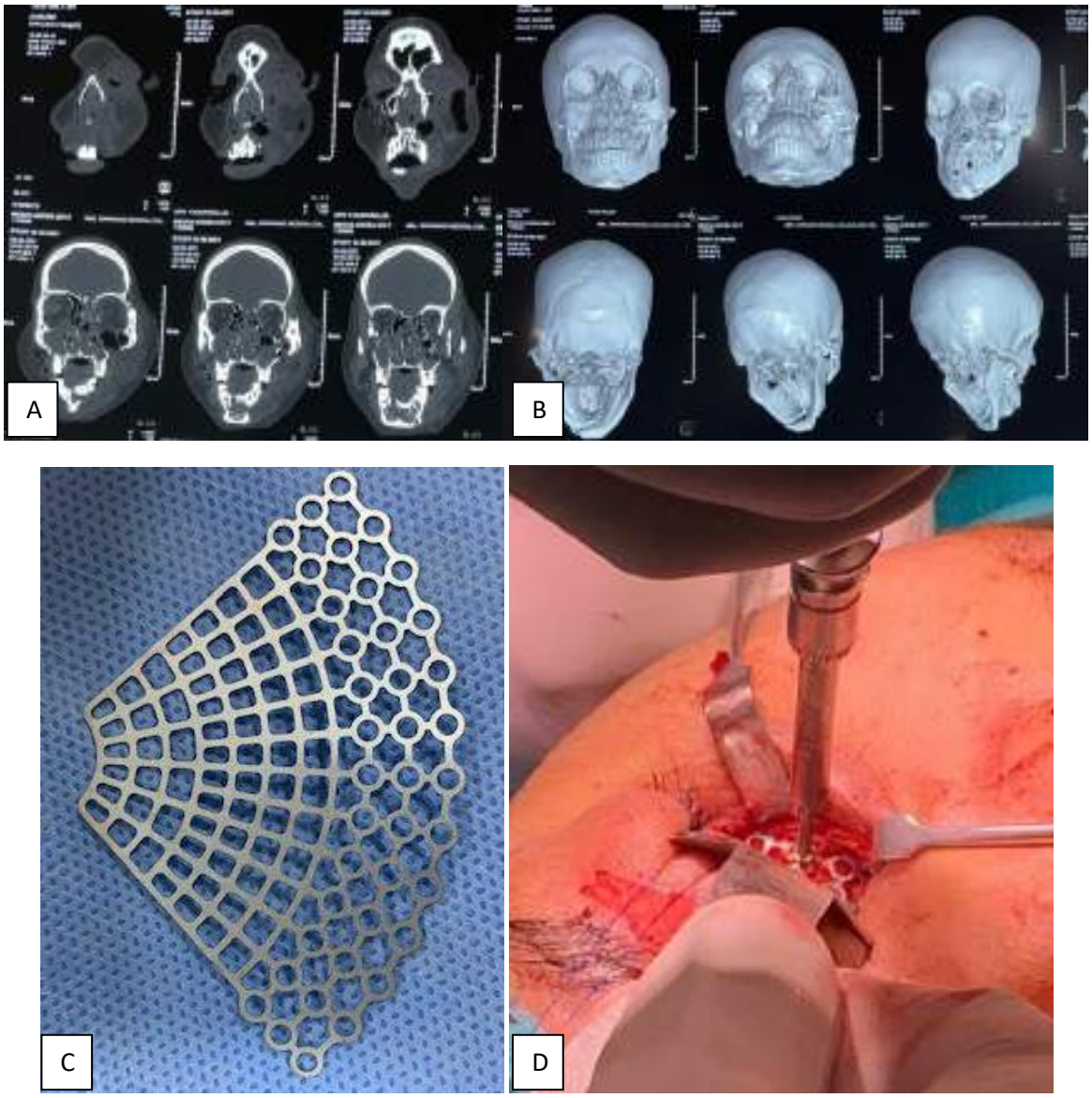
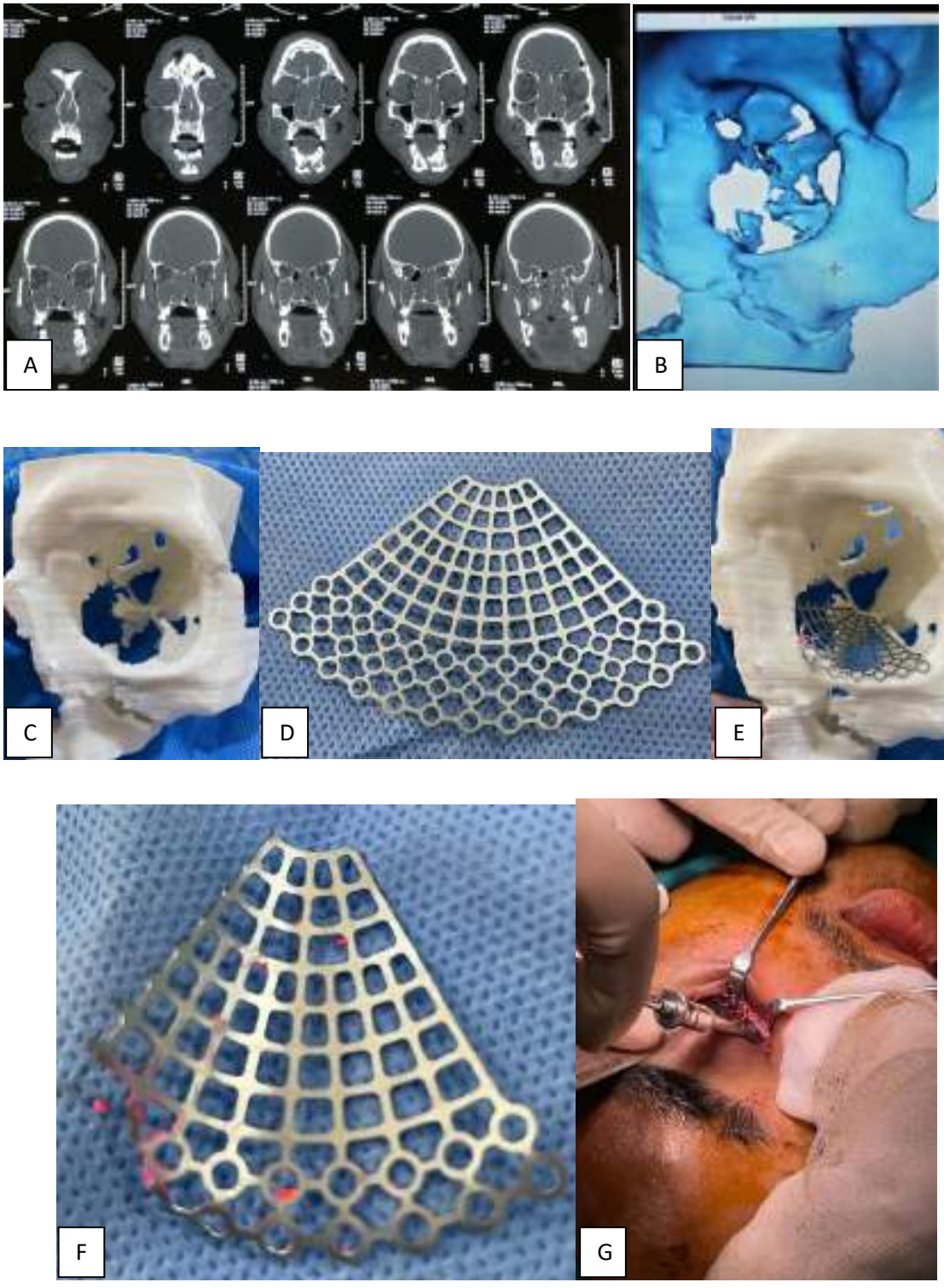


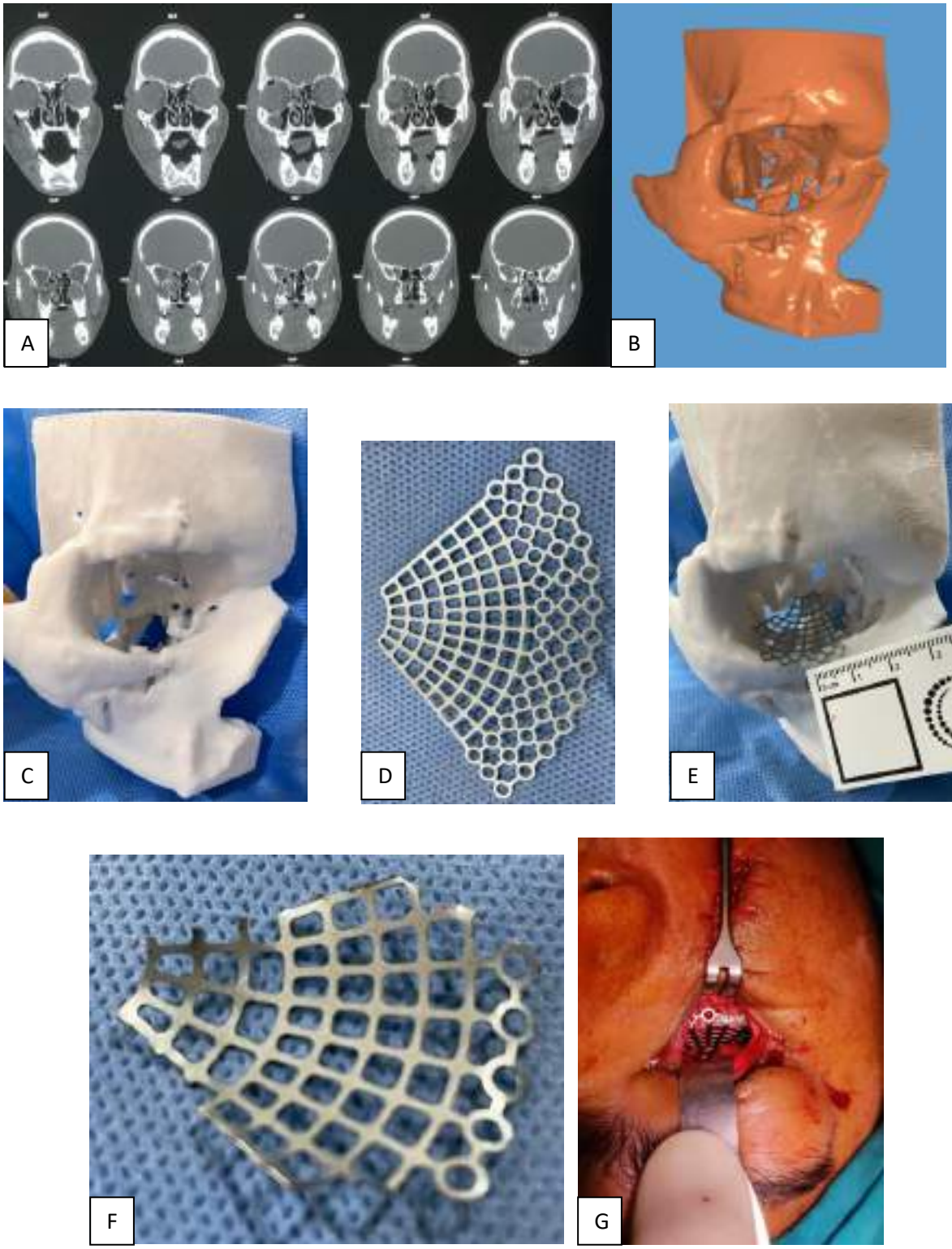
PICTURE 2: A. CT face (Coronal view) of a patient in Group A showing right orbital floor fracture with IR entrapment, B. 3D reconstructed CT scan showing right orbital floor fracture with inferior orbital rim involvement, C. Orbital floor fracture fixation plate, D. Intraoperative manipulation of plate for insertion onto the fracture site after multiple modifications done to the plate.



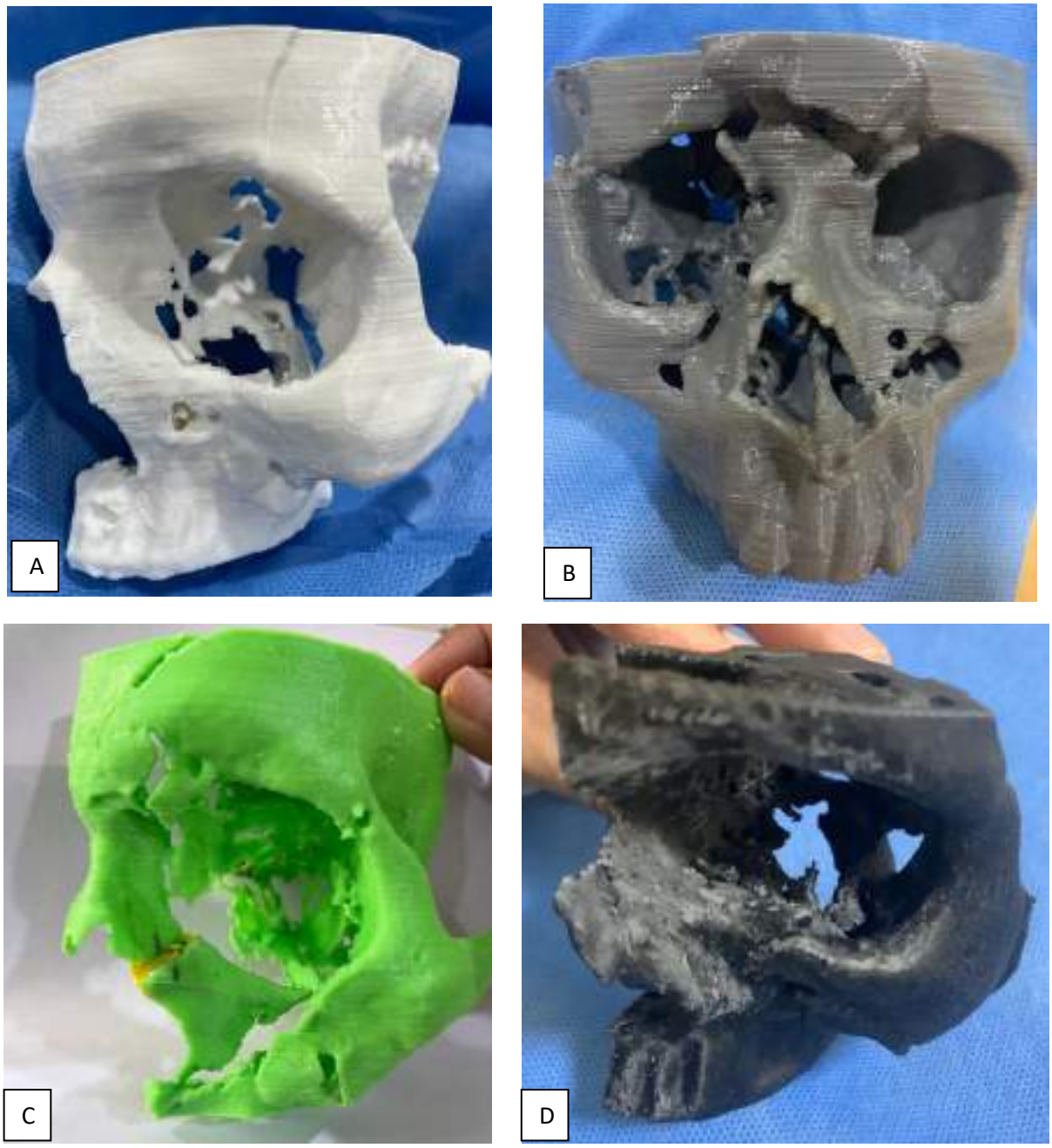
PICTURE 3: A. CT face (Coronal view) of a patient in Group A showing left orbital floor fracture with fat herniation and IR entrapment, B. 3D reconstructed CT scan showing left orbital floor fracture with multiple facial fractures, C. Orbital floor fracture fixation plate, D. Intraoperative fixation of plate with screws after modifying the plate twice.



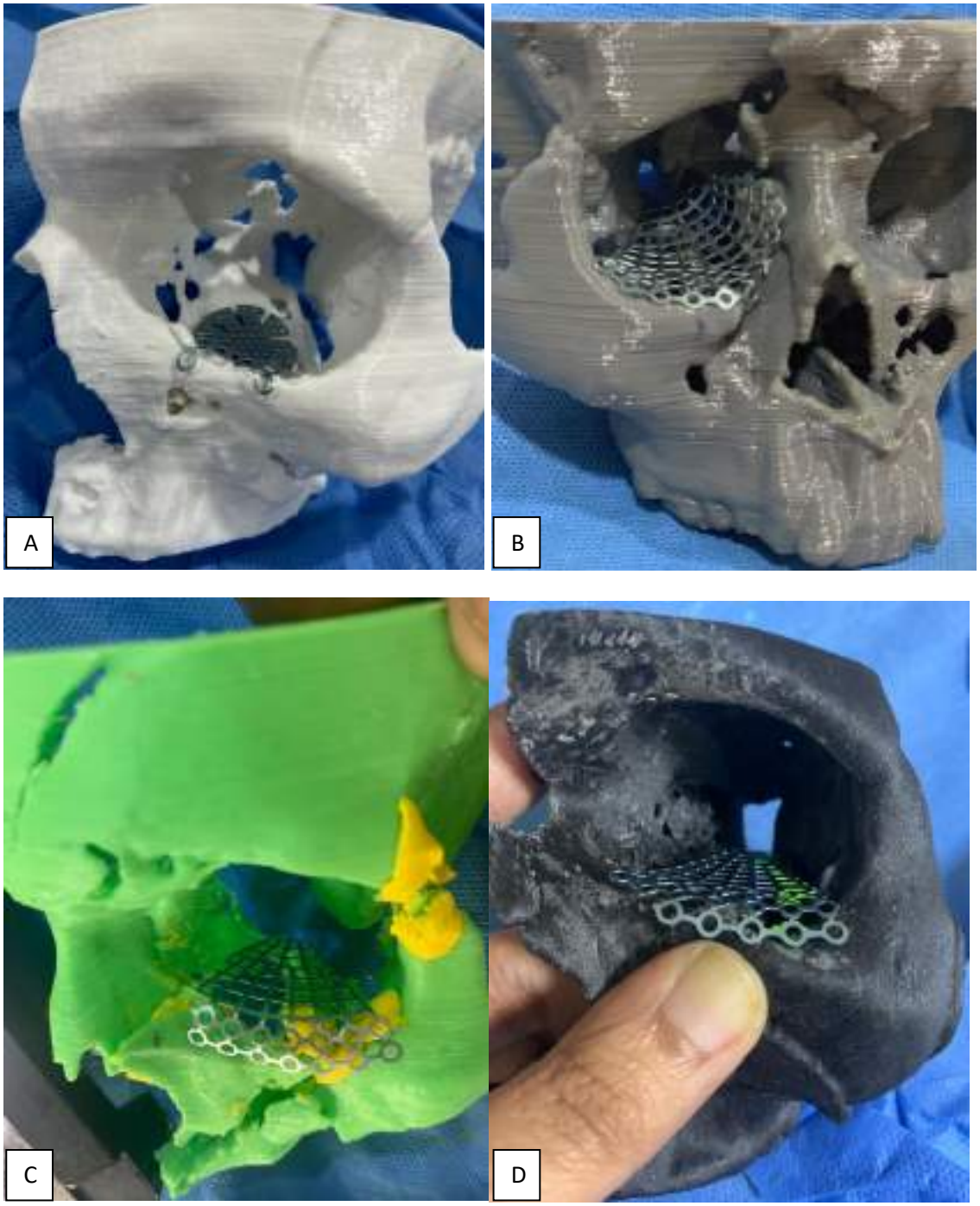
PICTURE 4: A. CT face (Coronal view) of a patient in Group B showing left orbital floor fracture with fat herniation, B. Creation of the 3D printed model using proprietary software (DICOM to STL), C. Final 3D printed model created using FDM technique, D. Orbital floor fracture fixation plate, E. Plate bent and cut preoperatively using the 3D printed model as template, F. Prebent plate ready to be resterilized before surgery, G. Intraoperative picture showing fixation of plate onto the fracture site without any additional manipulations.



PICTURE 5: A. CT face (Coronal view) of a patient in Group B showing right orbital floor fracture with fat herniation and IR entrapment, B. Creation of the 3D printed model using proprietary software (DICOM to STL), C. Final 3D printed model created using FDM technique, D. Orbital floor fracture fixation plate, E. Plate bent and cut preoperatively using the 3D printed model as template, F. Prebent plate ready to be resterilized before surgery, G. Intraoperative picture showing fixation of plate onto the fracture site without any additional manipulations.



PICTURE 6: 3D printed models showing orbital floor fracture with associated facial fracture in different patients of Group B.



PICTURE 7: Fixation plates contoured and cut according to fracture site using 3D printed model as template in different patients of Group B.

KEY TO MASTER CHART

B/L	Bilateral
D	Driver
DAI	Diffuse axonal injury
EDH	Extradural hemorrhage
F	Female
IVH	Intraventricular hemorrhage
L	Left
M	Male
N/A	Not Applicable
P	Passenger
PS	Parasymphyseal
R	Right
RTA	Road Traffic Accident
SAH	Subarachnoid hemorrhage
SDH	Subdural hemorrhage

Sr. No	MRD No	NAME	AGE	GENDER	CAUSE OF INJURY	Type of Vehicle(if RSA)	DRIVER/ PASSENGER	ALLOCATED TO GROUP A/B	REASON FOR DELAY IN SURGERY (ONLY GROUP B)	PERIORBITAL OEDEMA	SUBCONJUNCTIVAL HAEMORRHAGE
1	685369	TS	28	Male	RTA	Two Wheeler	D	A	N/A	Mild (R)	Present (R)
2	980617	K	59	Male	RTA	Four Wheeler	D	A	N/A	Marked(L)	Present(L)
3	1042337	PK	50	Female	RTA	Two Wheeler	D	A	N/A	Mild (L)	Present(L)
4	1058925	D	32	Male	RTA	Two Wheeler	P	A	N/A	Mild (R)	Absent
5	1095137	RK	30	Male	RTA	Two Wheeler	D	A	N/A	Marked (L)	Present(L)
6	960481	RK	30	Male	RTA	Two Wheeler	D	A	N/A	Mild (R)	Present (R)
7	1208384	S	31	Male	Fall	N/A	N/A	A	N/A	Mild (L)	Present(L)
8	1131613	MK	35	Male	RTA	Four Wheeler	P	A	N/A	Marked (L)	Present(L)
9	1136632	JS	46	Male	RTA	Two Wheeler	P	A	N/A	Mild (L)	Present(L)
10	1143184	NS	26	Male	RTA	Two Wheeler	D	A	N/A	Mild (L)	Present(L)
11	1162691	TS	41	Male	RTA	Hit by Four Wheeler while walking	N/A	A	N/A	Marked (R)	Present (R)
12	1159686	MA	33	Male	Fall	N/A	N/A	A	N/A	Mild	Present(L)
13	1166945	PS	25	Male	RTA	Two Wheeler	D	A	N/A	Marked (R)	Present (R)
14	1175415	RK	38	Male	RTA	Four Wheeler	D	A	N/A	Marked (L)	Present(L)
15	1193479	GS	32	Female	Fall	N/A	N/A	A	N/A	Marked (B/L)	Present (B/L)
16	1112515	S	29	Male	RTA	Two Wheeler	D	A	N/A	Mild (R)	Present (R)
17	1203156	SK	20	Male	RTA	Four Wheeler	P	A	N/A	Marked (L)	Present(L)
18	1217257	SS	35	Male	RTA	Two Wheeler	D	A	N/A	Mild (L)	Present(L)
19	1223000	MC	32	Male	Assault	N/A	N/A	A	N/A	Marked (B/L)	Present (B/L)
20	1224400	RS	20	Male	RTA	Two Wheeler	P	A	N/A	Mild (L)	Present(L)
1	907975	PG	30	Male	RTA	Two wheeler	D	B	SAH+SDH+IVH	Mild (R)	Present (R)
2	929867	JS	17	Male	Assault	N/A	N/A	B	Haemorrhagic contusion with Pneumocephalus	Marked (L)	Present (L)
3	934048	RPS	13	Male	RTA	Two wheeler	D	B	Diffuse cerebral oedema	Mild (R)	Present(R)
4	935857	G	23	Male	RTA	Two wheeler	P	B	SDH	Mild (L)	Absent
5	938754	MS	29	Male	RTA	Two wheeler	P	B	SDH	Mild (R)	Present (R)
6	971481	BSG	22	Male	RTA	Four Wheeler	D	B	EDH+DAI	Marked (R)	Present (R)
7	961212	S	25	Male	RTA	Four Wheeler	D	B	SDH + IVH	Marked (L)	Present(L)
8	984801	BS	60	Male	RTA	Hit by Two wheeler while walking	N/A	B	Cervical Vertebral Fractures with Cord oedema	Mild (B/L)	Present (R)
9	1015535	R	22	Male	RTA	Four Wheeler	D	B	SAH+IVH+Pneumocephalus with B/L Frontal contusions	Mild (B/L)	Present (B/L)
10	1064888	KK	18	Female	RTA	Four Wheeler	D	B	Right Hydropneumothorax with Left Lung Contusions	Marked (L)	Present(L)
11	1112465	R	22	Male	RTA	Two wheeler	D	B	SAH	Mild (B/L)	Present (B/L)
12	1129450	AS	30	Male	RTA	Four Wheeler	P	B	Bowel Perforation	Mild (L)	Present(L)
13	1143305	GS	30	Male	RTA	Hit by Four Wheeler while walking	N/A	B	SAH+SDH	Mild (L)	Present (L)
14	1143153	BS	36	Male	Fall	N/A	N/A	B	SDH	Mild (L)	Present (L)
15	1149108	AS	30	Male	RTA	Two wheeler	D	B	EDH with Diffuse Cerebral and Cerebellar oedema	Marked (L)	Present (L)
16	1158954	P	28	Male	RTA	Two wheeler	P	B	Pneumocephalus with haemorrhagic contusions	Mild (B/L)	Present (B/L)
17	1185430	L	72	Male	Fall	N/A	N/A	B	SDH	Mild (L)	Present (L)
18	1204200	K	25	Male	RTA	Two wheeler	D	B	SDH	Marked (L)	Present (L)
19	1208374	PS	19	Male	RTA	Two wheeler	D	B	SDH+EDH	Mild (R)	Present (R)
20	1223485	JR	20	Male	RTA	Two wheeler	D	B	SAH+SDH	Mild (L)	Absent

		CLINICAL FINDINGS												CT
									ORBITAL FLOOR DEFECT			FAT		
Sr. No	MRD No	ENOPHTHALMOS	TELECANTHUS	DIPLOPIA	ROM	INFRA ORBITAL STEP DEFORMITY	MALOCCLUSION	ORBITAL FLOOR FRACTURE	MAX AP OF DEFECT	MAX ML OF DEFECT	DEFECT AREA IN cm2	HERNIATION THROUGH THE DEFECT	IR ENTRAPMENT	
1	685369	Present (R)	Absent	Absent	Absent	Absent	Present	Present (R)	2.4	2	4.8	Present	Nil	
2	980617	Not Assessable	Present	Not Assessable	Not Assessable	Present (L)	Present	Present(L)	1.9	1.5	2.85	Nil	Present	
3	1042337	Absent	Absent	Present	Upward Gaze	Present (L)	Absent	Present(L)	2.8	1.7	4.76	Present	Present	
4	1058925	Absent	Absent	Absent	Absent	Present (R)	Present	Present (R)	2.2	1.5	3.3	Present	Present	
5	1095137	Not Assessable	Present	Not Assessable	Not Assessable	Present (L)	Present	Present(L)	3.3	2	6.6	Nil	Present	
6	960481	Present (R)	Absent	Present	Upward Gaze	Present (R)	Present	Present (R)	3	1.8	5.4	Present	Present	
7	1208384	Absent	Absent	Absent	Upward Gaze	Absent	Absent	Present(L)	2.8	1.5	4.2	Present	Present	
8	1131613	Not Assessable	Absent	Not Assessable	Not Assessable	Absent	Absent	Present(L)	2.9	2	5.8	Nil	Present	
9	1136632	Absent	Absent	Present	Absent	Present (L)	Absent	Present(L)	3.3	1.5	4.95	Nil	Present	
10	1143184	Present(L)	Absent	Absent	Absent	Present (L)	Present	Present(L)	3.1	1.6	4.96	Present	Nil	
11	1162691	Not Assessable	Absent	Not Assessable	Not Assessible	Present (R)	Absent	Present (R)	2.8	1.8	3	Nil	Present	
12	1159686	Absent	Absent	Present	Absent	Absent	Absent	Present(L)	2.4	2	4.8	Present	Present	
13	1166945	Not Assessable	Absent	Not Assessable	Not Assessable	Present (R)	Present	Present (R)	2.9	1.6	4.64	Nil	Present	
14	1175415	Not Assessable	Present	Not Assessable	Absent	Present (L)	Absent	Present(L)	2.5	1.7	4.25	Present	Present	
15	1193479	Not Assessable	Absent	Not Assessable	Not Assessable	Present (L)	Absent	Present(L)	2	1.9	3.8	Present	Present	
16	1112515	Present (R)	Absent	Absent	Absent	Present (R)	Present	Present (R)	2.9	1.6	4.64	Present	Nil	
17	1203156	Not Assessable	Absent	Not Assessable	Not Assessable	Absent	Absent	Present(L)	2.8	1.7	4.76	Nil	Present	
18	1217257	Present(L)	Absent	Absent	Absent	Present (L)	Absent	Present(L)	3	2	6	Present	Nil	
19	1223000	Not Assessable	Present	Not Assessable	Not Assessable	Absent	Present	Present (R)	2.5	2	5	Present	Present	
20	1224400	Absent	Absent	Present	Upward Gaze	Absent	Present	Present(L)	2	2.1	4.2	Present	Present	
1	907975	Present (R)	Absent	Absent	Upward gaze (R)	Present (R)	Absent	Present (R)	-	-	-	Present	Present	
2	929867	Not Assessable	Present	Not Assessable	Not Assessable	Present (L)	Absent	Present (L)	-	-	-	Nil	Present	
3	934048	Present	Present	Absent	Absent	Present (R)	Absent	Present (R)	-	-	-	Present	Nil	
4	935857	Absent	Absent	Present	Upward Gaze	Present (L)	Present	Present (L)	-	-	-	Nil	Present	
5	938754	Present (R)	Absent	Absent	Upward Gaze	Absent	Present	Present (R)	-	-	-	Present	Present	
6	971481	Not Assessable	Absent	Not Assessable	Not Assessable	Present (R)	Present	Present (R)	-	-	-	Present	Present	
7	961212	Not Assessable	Absent	Not Assessable	Not Assessable	Absent	Present	Present (L)	-	-	-	Nil	Present	
8	984801	Present (R)	Absent	Present	Upward Gaze	Present (R)	Present	Present (R)	-	-	-	Present	Present	
9	1015535	Present (L)	Absent	Present	Upward Gaze	Present (L)	Present	Present (L)	-	-	-	Present	Present	
10	1064888	Not Assessable	Present	Not Assessable	Not Assessable	Present (L)	Present	Present (L)	-	-	-	Nil	Present	
11	1112465	Present	Present	Absent	Absent	Present (B/L)	Absent	Present (L)	-	-	-	Present	Nil	
12	1129450	Absent	Absent	Present	Upward Gaze	Present (L)	Absent	Present (L)	-	-	-	Nil	Present	
13	1143305	Present (L)	Absent	Absent	Upward Gaze	Present (L)	Present	Present (L)	-	-	-	Present	Present	
14	1143153	Absent	Absent	Present	Upward gaze	Absent	Absent	Present (L)	-	-	-	Nil	Present	
15	1149108	Not Assessable	Absent	Not Assessable	Not Assessable	Present (L)	Absent	Present (L)	-	-	-	Present	Present	
16	1158954	Absent	Absent	Absent	Upward gaze	Present (R)	Absent	Present (R)	-	-	-	Nil	Present	
17	1185430	Present (L)	Absent	Absent	Upward gaze	Present (L)	Present	Present (L)	-	-	-	Present	Present	
18	1204200	Not Assessable	Absent	Not Assessable	Absent	Not Assessible	Present	Present (L)	-	-	-	Nil	Present	
19	1208374	Absent	Absent	Present	Absent	Present (R)	Absent	Present (R)	-	-	-	Nil	Present	
20	1223485	Present	Absent	Absent	Absent	Present (L)	Absent	Present (L)	-	-	-	Present	Nil	

		T FINDINGS						3D RECONSTRUCTED CT FINDINGS						
Sr. No	MRD No	IO RIM FRACTURE	MEDIAL ORBITAL WALL FRACTURE	MANDIBLE FRACTURE	MAXILLA FRACTURE	NASAL BONE FRACTURE	ZYGOMA FRACTURE	ORBITAL FLOOR FRACTURE (OF)	INFRAORBITAL RIM FRACTURE (IOR)	MEDIAL ORBITAL WALL FACTURE (MOW)	MANDIBLE FrACTURE	MAXILLA FRACTURE	NASAL BONE FRACTURE	ZYGOMA FRACTURE
1	685369	Nil	Nil	Nil	Nil	Nil	Nil	Present (R)	Nil	Nil	Nil	Nil	Nil	Nil
2	980617	Present(L)	Present(L)	Present (L PS)	Present (B/L)	Present (B/L)	Present (L)	Present(L)	Present(L)	Present(L)	Present (L PS	Present (B/L	Present (B/L)	Present (L)
3	1042337	Present(L)	Nil	Nil	Nil	Nil	Present (L)	Present(L)	Present(L)	Nil	Nil	Nil	Nil	Present (L)
4	1058925	Present (R)	Nil	Nil	Present (R)	Nil	Nil	Present (R)	Present (R)	Nil	Nil	Present (R)	Nil	Nil
5	1095137	Present(L)	Present(L)	Present (L PS)	Nil	Present (B/L)	Present (L)	Present(L)	Present(L)	Present(L)	Present (L PS	Nil	Present (B/L)	Present (L)
6	960481	Present (R)	Nil	Present (R Body)	Nil	Nil	Present (R)	Present (R)	Present (R)	Nil	resent (R Bod	Nil	Nil	Present (R)
7	1208384	Nil	Nil	Nil	Nil	Nil	Present (L)	Present(L)	Nil	Nil	Nil	Nil	Nil	Present (L)
8	1131613	Nil	Nil	Nil	Present (L)	Present (L)	Present (L)	Present(L)	Nil	Nil	Nil	Present (L)	Present (L)	Present (L)
9	1136632	Present(L)	Nil	Nil	Nil	Nil	Present (L)	Present(L)	Present(L)	Nil	Nil	Nil	Nil	Present (L)
10	1143184	Present(L)	Nil	Present (L Condylar)	Nil	Present (L)	Nil	Present(L)	Present(L)	Nil	sent (L Condy	Nil	Present (L)	Nil
11	1162691	Present (R)	Nil	Nil	Nil	Nil	Nil	Present (R)	Present (R)	Nil	Nil	Nil	Nil	Nil
12	1159686	Nil	Nil	Nil	Nil	Nil	Nil	Present(L)	Nil	Nil	Nil	Nil	Nil	Nil
13	1166945	Present (R)	Nil	Present (R Ramus)	Present (R)	Present (B/L)	Present (R)	Present (R)	Present (R)	Nil	esent (R Ram	Present (R)	Present (B/L)	Present (R)
14	1175415	Present(L)	Present(L)	Nil	Nil	Nil	Nil	Present(L)	Present(L)	Present(L)	Nil	Nil	Nil	Nil
15	1193479	Present(L)	Nil	Nil	Nil	Nil	Present (L)	Present(L)	Present(L)	Nil	Nil	Nil	Nil	Present (L)
16	1112515	Nil	Nil	Present (R Body)	Present (R)	Nil	Nil	Present (R)	Nil	Nil	resent (R Bod	Present (R)	Nil	Nil
17	1203156	Nil	Nil	Nil	Nil	Present (B/L)	Nil	Present(L)	Nil	Nil	Nil	Nil	Present (B/L)	Nil
18	1217257	Present(L)	Present(L)	Nil	Nil	Nil	Present (L)	Present(L)	Present(L)	Present(L)	Nil	Nil	Nil	Present (L)
19	1223000	Nil	Present (R)	Nil	Nil	Present (B/L)	Nil	Present (R)	Nil	Present (R)	Nil	Nil	Present (B/L)	Nil
20	1224400	Nil	Nil	Nil	Present (B/L)	Present (B/L)	Present (L)	Present(L)	Nil	Nil	Nil	Present (B/L	Present (B/L)	Present (L)
1	907975	Present (R)	Nil	Nil	Nil	Present (B/L)	Present (R)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
2	929867	Present (L)	Present (L)	Nil	Nil	Present (B/L)	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
3	934048	Present (R)	Present (R)	Nil	Present (R)	Present (R)	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
4	935857	Present (L)	Nil	Present(L Condylar)	Present (L)	Nil	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
5	938754	Nil	Nil	Nil	Present (B/L)	Nil	Present (R)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
6	971481	Present (R)	Nil	Present(L PS)	Present (B/L)	Nil	Present (R)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
7	961212	Nil	Nil	Present(L Condylar)	Present (B/L)	Nil	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
8	984801	Present (R)	Nil	Nil	Present (B/L)	Nil	Present (R)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
9	1015535	Present (L)	Nil	Present (R Body)	Present (L)	Present (L)	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
10	1064888	Present (L)	Present (L)	Present (R PS)	Present (L)	Present (B/L)	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
11	1112465	Present (B/L)	Present (L)	Nil	Present (B/L)	Present (B/L)	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
12	1129450	Present (L)	Nil	Nil	Nil	Present (L)	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
13	1143305	Present (L)	Nil	Present (Left Ramus)	Present (L)	Nil	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
14	1143153	Nil	Nil	Nil	Nil	Present (B/L)	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
15	1149108	Present (L)	Nil	Nil	Nil	Nil	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
16	1158954	Present (R)	Nil	Nil	Nil	Present (B/L)	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
17	1185430	Present (L)	Nil	Present (R PS)	Nil	Present (B/L)	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
18	1204200	Nil	Nil	Present(L PS)	Nil	Nil	Nil	N/A	N/A	N/A	N/A	N/A	N/A	N/A
19	1208374	Present (R)	Nil	Nil	Nil	Nil	Present (R)	N/A	N/A	N/A	N/A	N/A	N/A	N/A
20	1223485	Present (L)	Nil	Nil	Present (L)	Present (L)	Present (L)	N/A	N/A	N/A	N/A	N/A	N/A	N/A

		3D PRINTED MODEL FINDINGS				-	-	INTRAOPERATIVE FINDINGS			IM
		ORBITAL FLOOR DEFECT									
Sr. No	MRD No	MAX AP	MAX ML	DEFECT SIZE area in cm2	MODIFICATIONS DONE TO THE PLATE	PREOPERATIVE UNDERSTANDING OF INJURIES FOR WHICH PATIENT IS GOING TO UNDERTAKE THE SURGERY SCORE	TIME ELAPSED FROM TRAUMA TO SURGERY (days)	INTRAOPERATIVE _DURATION OF ORBITAL FLOOR FRACTURE RECONSTRUCTION (mins)	TOTAL OPERATING TIME (mins)	NO. OF ADDITIONAL BENDS TO PLATES	ANAESTHESIA RELATED (IF/ ANY)
1	685369	N/A	N/A	N/A	N/A	5	1	18	60	2	Nil
2	980617	N/A	N/A	N/A	N/A	5	2	20	130	2	Nausea
3	1042337	N/A	N/A	N/A	N/A	6	2	24	140	2	Nil
4	1058925	N/A	N/A	N/A	N/A	5	2	18	95	3	Nil
5	1095137	N/A	N/A	N/A	N/A	6	1	25	180	2	Nil
6	960481	N/A	N/A	N/A	N/A	4	1	15	100	1	Vomiting
7	1208384	N/A	N/A	N/A	N/A	7	1	12	90	0	Nil
8	1131613	N/A	N/A	N/A	N/A	9	2	15	105	2	Nil
9	1136632	N/A	N/A	N/A	N/A	5	1	18	80	1	Nil
10	1143184	N/A	N/A	N/A	N/A	5	1	22	200	2	Nil
11	1162691	N/A	N/A	N/A	N/A	5	2	12	70	1	Sore throat
12	1159686	N/A	N/A	N/A	N/A	6	2	15	75	0	Nil
13	1166945	N/A	N/A	N/A	N/A	6	1	12	150	1	Nil
14	1175415	N/A	N/A	N/A	N/A	5	1	25	180	3	Nil
15	1193479	N/A	N/A	N/A	N/A	5	2	14	60	1	Nil
16	1112515	N/A	N/A	N/A	N/A	7	1	12	120	2	Nil
17	1203156	N/A	N/A	N/A	N/A	4	2	16	180	1	Nil
18	1217257	N/A	N/A	N/A	N/A	9	1	22	210	2	Nil
19	1223000	N/A	N/A	N/A	N/A	5	2	14	90	1	Nil
20	1224400	N/A	N/A	N/A	N/A	4	1	18	70	2	Nil
1	907975	2.9	1.8	5.22	Yes	10	5	6	45	0	Nil
2	929867	1.9	1.5	2.85	Yes	10	4	12	70	1	Nil
3	934048	3	1.9	5.7	Yes	9	8	8	120	0	Nil
4	935857	2.2	1.5	3.3	Yes	9	4	6	180	0	Nausea, Vomiting
5	938754	3.3	2	6.6	Yes	10	6	5	120	0	Nil
6	971481	2.4	1.8	4.32	Yes	9	7	7	145	0	Nil
7	961212	2.8	1.5	4.2	Yes	10	5	5	80	0	Nil
8	984801	2.9	2	5.8	Yes	8	4	9	100	0	Nausea, Vomiting
9	1015535	3.5	1.8	6.3	Yes	10	7	6	150	0	Nil
10	1064888	3.1	1.6	4.96	Yes	8	6	5	240	0	Nil
11	1112465	2.8	1.8	5.04	Yes	7	3	8	135	0	Nil
12	1129450	2.4	2	4.8	Yes	10	5	6	60	0	Sore throat
13	1143305	3.1	1.9	5.89	Yes	9	6	5	180	0	Nil
14	1143153	2.5	1.8	4.5	Yes	10	5	5	110	0	Nil
15	1149108	2	1.9	3.8	Yes	10	8	6	90	0	Nil
16	1158954	2.9	1.6	4.64	Yes	10	4	7	40	0	Nausea, Vomiting
17	1185430	2.8	1.9	5.32	Yes	9	8	6	180	0	Nil
18	1204200	2	2	4	Yes	8	6	5	70	0	Nil
19	1208374	2.5	2	5	Yes	10	5	5	35	0	Nil
20	1223485	3	2.1	6.3	Yes	10	5	4	150	0	Sore throat

		MEDIATE POST OPERATIVE		FUNCTIONAL STABILITY ASSESSMENT												
				ENOPHTHALMOS		TELECANTHUS			OCCULAR MOVEMENTS			DIPLOPIA			C	
Sr. No	**MRD No**	**IMMEDIATE POST OPERATIVE COMPLICATIONS PROSTHESIS RELATED**	**FACIAL CONTOUR SYMMETRY**	**ONE WEEK**	**4 WEEKS**	**IMMEDIATE**	**ONE WEEK**	**4 WEEK**	**IMMEDIATE**	**ONE WEEK**	**4 WEEK**	**IMMEDIATE**	**ONE WEEK**	**4 WEEK**	**IMMEDIATE**	
1	685369	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
2	980617	Nil	Not assessable	Nil	Nil	Present	Present	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
3	1042337	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Satisfactory	
4	1058925	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
5	1095137	Nil	Not assessable	Nil	Nil	Present	Present	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
6	960481	Nil	Not assessable	Present	Present	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Satisfactory	
7	1208384	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Satisfactory	
8	1131613	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
9	1136632	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
10	1143184	Nil	Not assessable	Present	Present	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
11	1162691	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
12	1159686	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
13	1166945	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Satisfactory	
14	1175415	Nil	Not assessable	Nil	Nil	Present	Present	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
15	1193479	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
16	1112515	Nil	Not assessable	Present	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
17	1203156	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
18	1217257	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
19	1223000	Nil	Not assessable	Present	Present	Present	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
20	1224400	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
1	907975	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
2	929867	Nil	Not assessable	Nil	Nil	Present	Present	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
3	934048	Nil	Not assessable	Present	Present	Present	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
4	935857	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
5	938754	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
6	971481	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
7	961212	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
8	984801	Nil	Not assessable	Present	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Satisfactory	
9	1015535	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Satisfactory	
10	1064888	Nil	Not assessable	Nil	Nil	Present	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
11	1112465	Nil	Not assessable	Present	Nil	Present	Present	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
12	1129450	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
13	1143305	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
14	1143153	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
15	1149108	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
16	1158954	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
17	1185430	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Not Satisfactory	
18	1204200	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Present	Nil	Nil	Not Satisfactory	
19	1208374	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	
20	1223485	Nil	Not assessable	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	Nil	Nil	Nil	Satisfactory	

		)CCLUSION		FACIAL CONTOUR SYMMETRY		FACIAL EDEMA			PATIENT SATISFACTION	
Sr. No	**MRD No**	**ONE WEEK**	**4 WEEKS**	**ONE WEEK**	**4 WEEKS**	**IMMEDIATE**	**ONE WEEK**	**4 WEEKS**	**ONE WEEK**	**4 WEEKS**
1	685369	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Satisfied
2	980617	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Mild	Nil	Satisfied	Satisfied
3	1042337	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Satisfied
4	1058925	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
5	1095137	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Marked	Mild	Nil	Satisfied	Satisfied
6	960481	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Mild	Nil	Not Satisfied	Not satisfied (Enophthalmos)
7	1208384	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Satisfied
8	1131613	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Mild	Nil	Satisfied	Satisfied
9	1136632	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Satisfied
10	1143184	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Mild	Nil	Not Satisfied	Not satisfied (ectropion)
11	1162691	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Marked	Mild	Nil	Satisfied	Highly satisfied
12	1159686	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Satisfied
13	1166945	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Marked	Mild	Mild	Satisfied	Satisfied
14	1175415	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Mild	Mild	Not Satisfied	Not satisfied (Edema)
15	1193479	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Satisfied
16	1112515	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
17	1203156	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
18	1217257	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Mild	Nil	Satisfied	Satisfied
19	1223000	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Mild	Nil	Not Satisfied	Not satisfied (Enophthalmos)
20	1224400	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Marked	Nil	Nil	Not Satisfied	Satisfied
1	907975	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Marked	Mild	Nil	Satisfied	Highly satisfied
2	929867	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Mild	Nil	nil	Satisfied	Highly satisfied
3	934048	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Marked	Mild	Nil	Satisfied	Satisfied
4	935857	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
5	938754	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
6	971481	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
7	961212	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Not Satisfied	Satisfied
8	984801	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
9	1015535	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
10	1064888	Satisfactory	Satisfactory	Asymmetrical	Symmetrical	Mild	Nil	Mild	Not Satisfied	Not Satisfied (Ectropion)
11	1112465	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
12	1129450	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
13	1143305	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
14	1143153	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
15	1149108	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
16	1158954	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Satisfied	Highly satisfied
17	1185430	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
18	1204200	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Mild	Nil	Satisfied	Highly satisfied
19	1208374	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Mild	Nil	Nil	Highly satisfied	Highly satisfied
20	1223485	Satisfactory	Satisfactory	Symmetrical	Symmetrical	Marked	Mild	Nil	Highly satisfied	Highly satisfied

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Date 5/3/2021

The Principal,
DMC, Ludhiana

Subject: Approval of Plan of Thesis.

This is to inform you that the Faculty of Medical Sciences in its meeting held on 22.01.2021 has approved the plan of thesis of Dr Devika Rakesh, a student of your college for MCh Plastic & Reconstructive Surgery along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
A prospective comparative analysis of efficacy and accuracy of 3D printed model vs 3D reconstructed ct scan in patients with facial fractures

Supervisor
Dr. Ramneesh Garg
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Reconstructive Surgery,
DMCH, Ludhiana.

Co-Supervisor
Dr. Rajinder K. Mittal
Prof. & Head,
Dept. of Plastic &
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DMCH, Ludhiana.

Dr .Kavita Saggar

The student has to submit the three copies of thesis (along with PDF format) , to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She must directed to attach a photocopy of this letter with the forwarding letter while submitting thesis to the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic(, if any).

Dr. S P Singh MS(Oph)
Controller of Examinations

Note:

14. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*

A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY AND ACCURACY OF 3D PRINTED MODEL VS 3D RECONSTRUCTED CT SCAN IN PATIENTS WITH FACIAL FRACTURES

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

M.Ch

IN

PLASTIC AND RECONSTRUCTIVE SURGERY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES
FARIDKOT

MARCH, 2020

DR. DEVIKA RAKESH

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ABSTRACT OF PLAN OF THESIS

Title	A Prospective Comparative Analysis of efficacy and accuracy of 3D Printed model vs 3D Reconstructed CT scan in patients with facial fractures
For the degree of	MCh Plastic and Reconstructive Surgery
Name of the candidate	Dr. Devika Rakesh
Supervisor	Dr. Ramneesh Garg, Professor , Department of Plastic and Reconstructive Surgery , DMCH, Ludhiana
Co-supervisor	Dr. Rajinder K Mittal, Professor and Head, Department of Plastic and Reconstructive Surgery, DMCH, Ludhiana Dr. Kavita Saggar, Professor & Head, Department of Radiodiagnosis, DMCH, Ludhiana
Institution	Dayanand Medical College & Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction: Patients with unstable or comminuted fractures need to be reduced and rigidly fixed with titanium plates and screws .Bending and shaping the plates is performed by free hand intraoperatively which may take a lot of operative time and may not snugly fit all the fractures. Therefore for these cases an appropriate imaging tool used preoperatively which can aid in intraoperative fixation of facial fractures is quintessential.

Aim of Study: Our aim is to compare the efficacy and accuracy of 3D Printed model vs 3D reconstructed CT Scan in patients with facial fractures in terms of intraoperative ease of fixation, accuracy of fixation, intraoperative time, post operative facial contour symmetry ,functional stability of facial skeleton and patient satisfaction.

Materials & Methods: The prospective study will be carried out on 40 patients with facial fractures allocated in two groups of 20 patients each. Group A will comprise of those patients who can be taken up for open reduction and fixation of fractures immediately , they will undergo CT face with 3D reconstruction preoperatively . Group B will comprise of those patients who cannot be taken up immediately for the surgery and will get a plain CT face done which will be , their CT data will be imported to the 3D printer for creation of specific 3D printed models using FDM (Fused deposition modelling technique) and procured from Punjab Engineering College (PEC) within 72 hours which will aid in preoperative bending and shaping of plates used for fracture reduction. Various intraoperative and post operative parameters will be compared among patients in the two groups.

Clinical Significance: We believe that we can achieve improved bony fixation, shorter intra-operative time, superior clinical outcome without significant increase in overall cost of treatment with the use of 3 D printed models over 3D reconstructed CT scans done preoperatively in patients with facial trauma.

Keywords: Facial fractures, 3D Reconstructed CT Scan, 3D printed model, Operative time.

(Signature) Candidate	(Signature) Co-Supervisor	(Signature) Co-Supervisor	(Signature) Supervisor	(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY AND ACCURACY OF 3D PRINTED MODEL VS 3D RECONSTRUCTED CT SCAN IN PATIENTS WITH FACIAL FRACTURES"** exist in the Department of Plastic and Reconstructive surgery, DMC&H, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis is genuine and is collected by the candidate herself under our supervision and guidance.

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APPROVAL PROFORMA
BY RESEARCH & ETHICAL COMMITTEE
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Topic of Thesis	A Prospective Comparative Analysis of efficacy and accuracy of 3D Printed model vs 3D Reconstructed CT scan in patients with facial fractures
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PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

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3	COURSE OF STUDY AND SUBJECT	MCh, Plastic and Reconstructive surgery
4	DATE OF ADMISSION OF COURSE	27/08/2019
5	TITLE OF THE TOPIC	A Prospective Comparative Analysis of efficacy and accuracy of 3D Printed model vs 3D Reconstructed CT scan in patients with facial fractures

6 BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Patients with complex facial injuries or defects require reconstruction using hardware to restore facial contour and stability. Unstable or comminuted craniofacial fractures need to be reduced and rigidly fixed with titanium plates and screws. Bending and shaping the plates is usually performed by free-hand intraoperatively which may take a lot of operative time. Morever, bent plates may not snugly fit all the fractures. Therefore, for these cases an appropriate imaging tool used preoperatively which can aid in intraoperative fixation of facial fractures is quintessential. Medical imaging has evolved dramatically in the past few decades. 3D visualization, multiplanar reformation and image navigation help radiology to be pivotal for many clinical disciplines.[1] Today's image guided surgeries illustrate how radiology has become integrated in a therapeutic team together with different surgical specialities. However, we are limited by the use of flat screens for the visualization of three- dimensional imaging data. An emerging technique, referred to as 3D printing or rapid prototyping, overcomes this limitation by producing graspable three-dimensional objects.[2]

3D Reconstructive CT

For many years, physicians relied on two dimensional (2D) radiographs of the facial skeleton to evaluate facial injuries which were relatively difficult to interpret because of the superimposition of bony landmarks and defects.[3]

Next, three-dimensional images were created from the original 2D slices which were found to assist in the visualization of large comminuted, displaced, and complex fractures involving multiple planes, particularly in regard to the midface.[4] To accurately assess symmetry and fracture lines, reconstructed images had to be angulated carefully to exclude any false positives.[5] 3D scans enable clinicians to better assess the localization of bone fragments and their direction of displacement. However they are not indicated, for small fractures of the orbital floor or isolated fractures of the maxillary wall, in which the

fracture is limited to one plane. Here, examining 3D scans alone can give false-negative results.[5,6] With this in mind, it is useful to think of 3D imaging as a complementary study that can add important information to multiplanar imaging.

3D Printed model

3D printing is a methodology using three-dimensional CAD data sets for producing 3D haptic physical model. It involves the process of additive manufacturing which involves conversion of computerized tomography or magnetic resonance imaging (MRI) data, which is in data imaging and communications in medicine (DICOM) format into standard tessellation language (STL) format using a proprietary software.[7] Once in a printable format, the file can be imported to the 3 D printer for creation of the specific model. It is also referred to as rapid prototyping, solid free form; computer automated or layered manufacturing depending on the kind of production method used. The principle of rapid prototyping is to use 3D computer models for the reconstruction of a 3D physical model by the addition of material layers.[8] With additive fabrication, the machine reads in data from a CAD drawing and lays down successive layers of liquid, powder, or the sheet material, and in this way builds up the model from a series of cross sections. These layers, which correspond to the virtual cross section from the CAD model joined together, create the final shape. The primary advantage of additive fabrication is its ability to create almost any complex shape or geometric feature.

Rapid prototyping includes a number of established manufacturing techniques and a multitude of experimental technologies either in development or used by small groups of individuals. Established rapid prototyping techniques are: Stereoli- thography (SLA), Selective Laser Sintering (SLS), Fused Deposition Modeling (FDM), Laminated Object Manufacturing (LOM), Inkjet printing.

The rationale for this study is to explore the efficacy and accuracy of 3 D models of patients with facial fractures as aids for facial fracture reconstruction and compare it with the efficacy of 3 D reconstruction scans done alone in patients with facial fractures. We believe that we

can achieve improved bony fixation, shorter intra-operative time, superior clinical outcome without significant increase in overall cost of treatment.

6.2 REVIEW OF LITERATURE

3D printing and computer software planning are gaining extended applications in facial plastic and reconstructive surgery. The combination of computer-aided design and manufacturing (CAD- CAM) has provided surgical models for pre surgical planning, plate contouring, and customized patient-specific implants (PSIs). Reported benefits have included increased accuracy of reconstruction, decreased intraoperative time, decreased fatigue of the metal, and ease of use.[9-11]

3D printing applications in surgical planning including accurate anatomic bio models, surgical cutting guides in reconstruction, and patient-specific implants fabrication. 3D printing technology also offers access to well tolerated, reproducible, and high-fidelity/patient-specific models for surgical training. Emerging research in 3D biomaterial printing have led to the development of biocompatible scaffolds with potential for tissue regeneration in reconstruction cases involving significant tissue absence or loss. Major limitations of utilizing 3D printing technology include time and cost, which may be offset by decreased operating times and collaboration between departments to diffuse in-house printing costs.

Berens et al. (2016)[12] described creating a patient- specific pediatric costal cartilage model for microtia skills training by utilizing CAD and 3D printing. In particular, the model aimed to simulate auricular framework reconstruction by carving the costal cartilage model. In their study, their novel starch:silicone composite created patient specific costal cartilage model was noted be similar to rib in geometry, carving characteristics, and pliability, though less in suturing characteristics and texture, as assessed by experienced microtia surgeons. Previously Magritz and Siegert (2014) [13] described a 3D printed training model for rib graft carving.

Besides bony and cartilaginous training models, 3D printed simulation models focusing on soft tissue skills have also been reported. Zabaneh et al. (2009)[14] reported a novel prototype of a patient specific rhinoplasty surgical training simulator. Using data from a patient with a

prominent dorsal nasal hump, a multimaterial anatomic model was designed and printed using FDM technology. Their model used acrylonitrile butadiene styrene (ABS) for the bony construct and different types of medical grade silicone for the cartilage, skin, and mucosa. Their model demonstrates the ability to create surgical trainers of varying materials for different tissues, and provides an anatomically accu- rate model for surgical practice.

Reuben et al.(2005)[15] reported that individuals at different levels of experience showed differential appreciation for the traumatic injuries illustrated by radiograph, 2D CT, and 3D reconstruction. Non-radiologist viewers correctly diagnosed the fractures in 75.7% of 3D cases, 71.5% of radiographs and 64.7% of conventional CT. Viewers showed a preference for 3D CT over conventional CT over radiograph in a survey conducted as a part of this study, and a similar survey performed by Alder also demonstrated that surgeons preferred 3D reconstructions to 2D versions for treatment planning.

King et al. (2018) [16] compared the intraoperative time and operating room costs between patients with mandibular fractures treated with traditional adaptation and fixation and patients treated with preadapted plates created with on-site 3-dimensionally printed models. The 38 patients included in the study had a mean age of 39.6 years, and male patients comprised 81.6%. The mean time for intraoperative plate adaptation was 22.8 ` 2.1 minutes in the control group and 6.9 ` 0.3 minutes in the experimental, 3D printed group ($P < .0001$). In the experimental group, 4 patients (21%) required a single intraoperative corrective bend. The calculated average cost per patient based on the average operating costs was $2,306.45 in the control group and $698.00 in the experimental group. Hence, they concluded that the use of 3D printers for fabrication of models to prebend maxillofacial reconstruction plates is associated with decreased operating room time and costs.

Rodt T et al [17] (2016) Evaluated surface (SR) and volume rendering (VR) in 3D-CT of facial fractures, Multislice CT was obtained in 22 patients with facial fractures using two data acquisition protocols. Five

SR and VR post-processing protocols were applied. Five assessors independently evaluated the quality of visualization of the fracture gap and dislocated fragments as well as the overall image quality using a five-point rating scale. The potential benefit of the 3D- images for radiological diagnosis and presentation was evaluated. The influence of the data acquisition protocol was analysed. SR in general achieved better evaluation scores than VR at corresponding thresholds. Variation of evaluation scores for all criteria was found for SR and VR depending on the segmentation threshold. Apart from the overall image quality no significant influence of the data acquisition technique was found for the evaluated criteria.

Kaur J., & Chopra R. (2010) [18] included 100 patients of mid face fractures in this study. After clinical examination patients were subjected to conventional radiographs. To arrive at correct diagnosis and treatment plan, each patient was subjected to 3D reconstruction. Out of hundred patients of maxillofacial trauma 80% were male and 20% were females. Based on the etiology road traffic accidents (75%) were the most common, followed by assault (16%), fall (7%) and sports related accidents (2%). In 28 cases (28%) 3D CT had significant bearing in final diagnosis and treatment planning of mid face fractures. They concluded that 3D CT is valuable in case of severe facial injury, enabling a clear perception of extent of major fracture line and resulting displacement of fragments. So this new modality permits preoperative analysis and surgical planning as compared to conventional radiography in case of mid face fractures.

Sekou S, et al (2017) [19] reported the benefit of Computer Tomography (CT), reverse engineering (RE) and rapid prototyping (RP) in individual implant production for maxillofacial surgery. They studied some clinical cases where virtual models have been used for surgical preparations and 3D printing models for manufacturing of implants. A 40 year old women patient with nose defect admitted for defect reconstruction, 50 year old man with a large mandible defect who underwent mandible reconstruction with intraoperative reconstruction plate which fractured leading to non union admitted for use of a customized design of

prosthesis for restoration of bony continuity and facial contour, 43 year old women who underwent extended surgical resection for mandibular osteosarcoma and reconstruction with traditional mandibular titanium plate which was unable to support the mandibular morphology admitted for restoration of mandibular continuity, facial contour and the oral function, 34 year old female with adenocarcinoma maxilla who underwent maxillary bone resection admitted for facial deformity correction. All these cases were treated with reconstruction implant prefabricated using 3 D printing. There were no complications observed in all patients who underwent reconstruction using 3D Printing implants in 10 year of follow up, all of these patients regained full oral function .They concluded that use of 3D printing technique have facilitated the mandible reconstruction surgery , offer a better life to the patients.

Sieira et al. (2015) [20] in their study compared patients treated with conventional intraoperative plate bending for mandibular reconstruction with patients who underwent free fibular flap using rapid prototype modelling and precontoured titanium plates .Their study demonstrated a statistically significant decrease in dental malocclusion, exposure of hardware and operating time (mean reduction of 42 minutes) for patients that was reconstructed using 3 D printing technology with similar complication rates.

Azuma et al. (2014) [21] compared aesthetic outcomes of prebent mandibular reconstruction plates using 3D printed models versus intraoperative plate bending in 28 patients. In their study, 12 patients were reconstructed with 3D printed model based prebent plates and 16 patients were treated with intra-operative plate bending. The resected site was then compared to the unaffected side using panoramic tomography postoperatively to determine symmetry. They observed the group treated with 3D printed prebent plates demonstrated significantly better postoperative facial contour symmetry ($P<0.05$) than the group treated with intraoperative bent plates.

6.3 AIMS AND OBJECTIVES OF THE STUDY

1. To compare the intraoperative ease of use of fixation device and accuracy of bony fixation in patients with facial fractures undergoing 3D Printed Model vs 3D Reconstructed CT scan preoperatively
2. To compare the intraoperative time (time of insertion of plate) amongst patients with facial fractures undergoing 3D Printed Model vs 3D Reconstructed CT scan preoperatively
3. To compare the post operative outcome clinically in terms of facial contour symmetry and functional stability of facial skeletal framework in the patients with facial fractures.
4. To compare the level of understanding patient had preoperatively about the injuries for which the patient is going to undertake the surgery

7.0 MATERIALS AND METHODS

7.1 SOURCE OF DATA:

This prospective study will be conducted on 40 patients with facial fractures attending the Emergency or OPD at Dayanand Medical College and Hospital Ludhiana from March 2020 to March 2022 willing to be a part of the study. Those part of the study shall have to satisfy the inclusion criteria and none of the exclusion criteria.

7.2 METHOD OF COLLECTION OF DATA

Inclusion criteria:

(1) Patients with facial fractures

(2) Patients with comminuted displaced fractures

(3) Patients not fit to be taken up for immediate surgical intervention (Group B)

Exclusion criteria:

(1) Patients not fit for General Anesthesia

(2) Situations where delay of surgery is going to be detrimental for patient's health

(3)Patients with coagulation disorders

(4) Isolated non comminuted fracture of any facial bone

(5) Patient with isolated nasal bone fracture

The patients in the study will be divided into two groups of 20 patients each :

Group A –Patients with facial trauma who can be taken up for open reduction and fixation of facial skeleton fractures immediately.

Group B- Patients with facial trauma who cannot be taken up immediately for any surgical intervention.

Group A patients will get a CT face with 3 D reconstruction done.

Group B patients will get a CT face done in our institution and the CT data which is in data imaging and communications in medicine (DICOM) format will be converted into standard tessellation language (STL) format using a proprietary software which will then be imported to the 3D printer for creation of the specific 3D printer model by laying down layers of polylactic acid using FDM (Fused Deposition Modelling) technique. These 3 D printed models will be procured from PEC

(Punjab engineering college). Payment for which will be made through online transfer. These 3D Printed models will be available within 72 hours of sending the DICOM data.

Patients in both the groups will be taken up for open reduction and internal fixation of facial skeletal fractures.

In Group A patients, the fractures will be repaired in the usual fashion i.e. using plates that are bent by free hand intraoperatively

While in Group B patients, the printer models made will be used as templates for bending and shaping the plates preoperatively for stabilizing the fracture.

The template will be placed in a sterile plastic bag to avoid direct contact with the reconstruction plate. A plate will be selected and adapted to the printed model preoperatively

The plate will be processed and sterilized to allow for human implantation. Once in the OR, the fracture site will be accessed in the typical fashion and the plate adaptation evaluated. Adjustments will be made if needed, and the plate will then be fixated in place using locking screws, followed by closure of the incision.

Outcome: Preoperative understanding of the patients in both the groups about the injuries for which they are going to undertake the surgery will be assessed using a score of 1 to 10. and will be compared among both the groups.

Various intra-operative parameters will be compared among patients in the two groups after matching parameters of pattern and site of fractures – including intra-operative time, number of adjustments required for adaptation, the total length of time for plating, starting when the fracture is completely reduced and ending when the last screw is placed for fixation, anesthesia time, accuracy of fixation of fractures, decreased fatigue of fixation plate metal and ease of use of fixation plates.

Post-operatively facial contour symmetry will be assessed clinically and patient satisfaction, subjectively in both the groups and a comparison between the two groups will be made on follow up visits (week 1, week 4).

Overall cost of treatment will be compared between the two groups.

STATISTICAL ANALYSIS: Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using Student t-test and Mann Whitney U test for independent samples for parametric and non-parametric data respectively. For comparing categorical data, Chi square ($\chi 2$) test will be performed and exact test will be used when the expected frequency is less than 5.A probability value (p value) less than 0.05 was considered statistically significant. A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations will be done using SPSS (Statistical Package for the Social Science) SPSS 21 version statistical program for Microsoft Windows.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

NO

7.4 HAS ETHICAL CLEARENCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

ATTACHED HEREWITH

8.0 LIST OF REFERENCES

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PROFORMA

S. No. MRD No.

NAME AGE/SEX

FATHER'S/ HUSBAND'S NAME

CHIEF COMPLAINT

HISTORY OF PRESENT ILLNESS:

PAST HISTORY

ALLOCATED TO GROUP A/B-

REASON FOR DELAY IN SURGERY (ONLY GROUP B)

PREOPERATIVE

CLINICAL FINDINGS

CT FINDINGS

3D RECONSTRUCTED CT FINDINGS

3D PRINTED MODEL FINDINGS

Signature of Candidate **Signature of Supervisor**

PREOPERATIVE UNDERSTANDING OF INJURIES FOR WHICH PATIENT IS GOING TO UNDERTAKE THE SURGERY –

SCORE - 1----------5----------10

POOR FAIR GOOD

OPERATION RECORD

DATE

PROCEDURE EXECUTED -

INTRAOPERATIVE FINDINGS

FRACTURE SITE

DURATION OF FRACTURE FIXATION

TOTAL OPERATING TIME

NO. OF DOSES OF MUSCLE RELAXANT

NO. OF ADDITIONAL BENDS TO PLATES (IF/ANY)

POST OPERATIVE

1) IMMEDIATE COMPLICATIONS

COMPLICATIONS

ANAESTHESIA RELATED (IF/ ANY) :

PROSTHESIS RELATED (IF/ ANY):

FACIAL CONTOUR SYMMETRY

FUNCTIONAL STABILITY ASSESSMENT

ENOPHTHALMOS (ORBITAL FLOOR FRACTURES)

Signature of Candidate **Signature of Supervisor**

TELECANTHUS/ PSEUDOTELECANTHUS (MEDIAL ORBITAL WALL FRACTURES:

OCCLUSION (MAXILLARY/MANDIBULAR FRACTURES):

2) FOLLOW UP AT 1 WEEK

FACIAL CONTOUR SYMMETRY

FUNCTIONAL STABILITY ASSESSMENT

ENOPHTHALMOS (ORBITAL FLOOR FRACTURES)

TELECANTHUS/ PSEUDOTELECANTHUS (MEDIAL ORBITAL WALL FRACTURES:

OCCLUSION (MAXILLARY/MANDIBULAR FRACTURES):

FACIAL EDEMA

PATIENT SATISFACTION- NOT SATISFIED SATISFIED VERY SATISFIED

3) FOLLOW UP AT 4 WEEKS

FACIAL CONTOUR SYMMETRY

FUNCTIONAL STABILITY ASSESSMENT

ENOPHTHALMOS (ORBITAL FLOOR FRACTURES)

TELECANTHUS/ PSEUDOTELECANTHUS (MEDIAL ORBITAL WALL FRACTURES:

OCCLUSION (MAXILLARY/MANDIBULAR FRACTURES):

FACIAL EDEMA

PATIENT SATISFACTION- NOT SATISFIED SATISFIED VERY SATISFIED

Signature of Candidate **Signature of Supervisor**

INFORMED PATIENT CONSENT

Date: _____

I.....D/o, W/o, S/o.....
am willing to participate in the study **"A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY AND ACCURACY OF 3D PRINTED MODEL VS 3D RECONSTRUCTED CT SCAN IN PATIENTS WITH FACIAL FRACTURES"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

.....
Signature of the Witness

.....
Signature of the patient

Name:

Signature of Candidate

Signature of Supervisor

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य "**A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY AND ACCURACY OF 3D PRINTED MODEL VS 3D RECONSTRUCTED CT SCAN IN PATIENTS WITH FACIAL FRACTURES**" में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

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गवाह के हस्ताक्षर रोगी के हस्ताक्षर/अंगूठे का निशान

नाम: नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫ਼ਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

"A PROSPECTIVE COMPARATIVE ANALYSIS OF EFFICACY AND ACCURACY OF 3D PRINTED MODEL VS 3D RECONSTRUCTED CT SCAN IN PATIENTS WITH FACIAL FRACTURES" ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

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ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ